Using Theory of Change to design and evaluate complex mental health interventions in low and middle income countries: the case of PRIME

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Declarations

I, Erica Breuer, present this thesis in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD) in the Department of Psychiatry and Mental Health, Faculty of Health Sciences, University of Cape Town. The work on which the thesis is based is original research led by me and has not, in whole or in part, been submitted for another degree at this or any other university. The content of the thesis is entirely my work, and in the case of multi-authored published papers, constitutes work for which I led the intellectual effort and was the lead author.

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1. Breuer E, Lee L, De Silva M and Lund C. Using theory of change to design and evaluate public health interventions: a systematic review. Implementation Science. 2016;11(1):1. (Chapter 2)

2. Breuer E, De Silva M, Fekadu A, Luitel N, Murhar V, Nakku J, Petersen, I and Lund, C. Using workshops to develop theories of change in five low and middle income countries: lessons from the programme for improving mental health care (PRIME). International Journal of Mental Health Systems. 2014;8(1):15. (Chapter 3)

3. Breuer E, De Silva MJ, Shidhaye R, Petersen I, Nakku J, Jordans MJ, Fekadu, A and Lund, C. Planning and evaluating mental health services in low-and middle-income

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5. Erica Breuer, Mary De Silva and Crick Lund, Theory of Change for complex mental health interventions: 10 lessons from the Programme for Improving Mental Healthcare (Submitted to Global Mental Health) (Chapter 6)

My contribution to the multi-authored papers is further outlined in the Section 1.8 of this thesis.

This thesis/dissertation has been submitted to the Turnitin module and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor.

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Ethical approval

Ethics approval was obtained from the Human Ethics Research Committee of the Faculty of Health Sciences at the University of Cape Town (REC Ref:247/2013) (Appendix 1.2). Additional ethical approval was obtained where necessary from local ethics committees in each study country: Institutional Review Board of the College of Health Sciences of Addis Ababa University; Sangath Institutional Review Board; Indian Council of Medical Research; Nepal Health Research Council; Biomedical Research Ethics Committee, University of Kwa-Zulu Natal; Research Ethics Committee of the School of Medicine, College of Health Sciences, Makarere University; and the National Council of Science and Technology, Uganda.

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List of Abbreviations

CIDT	Community Informant Detection Tool
FCHV	Female Community Health Volunteer
LMIC	Low and Middle Income Countries
MHCP	Mental Health Care Plan
mhGAP	WHO Mental Health Gap Action Programme
MRC	Medical Research Council, UK
NGO	Non-governmental Organisation
PHC	Primary Health Care
PHI	Public Health Intervention
PRIME	Programme for Improving Mental Health Care
RCT	Randomised Controlled Trial
ToC	Theory of Change
VDC	Village Development Committees
WHO	World Health Organisation

Abstract

Background

Many health interventions are complex and consist of several interacting components (Medical Research Council 2008). These components include multiple causal strands, outcomes and levels of governance and may result in unexpected outcomes and non-linear change (Glouberman and Zimmerman 2002). As such they present challenges to the design and evaluation of complex health interventions. Although broad theoretical guidance has been developed by the UK Medical Research Council (MRC) (Craig, Dieppe et al. 2008), it contains little practical guidance and has been criticised for not including theory driven approaches to evaluation such as Theory of Change (ToC) (Anderson 2008). De Silva, Breuer et al. (2014) have proposed that ToC may complement the MRC guidance on complex health interventions.

Methods

This study explores how ToC can strengthen the design and evaluation of complex health interventions using the example of The Programme for Improving Mental Health Care (PRIME). PRIME is a research programme which aimed to develop, implement and evaluate the integration of mental health into primary health in districts or sub-districts in Ethiopia, India, Nepal, South Africa and Uganda. A ToC approach was used in addition to other approaches to design and evaluate these complex mental health interventions. Firstly, I conducted a systematic review to determine the extent to which ToC has been used to design and evaluate public health interventions. Secondly, I compared the process of developing the ToC between all five PRIME countries and reflected on the value of ToC

workshops using a framework analysis of workshop documentation and interviews with facilitators. Thirdly, I explored the development of the ToCs within the programme as a whole and the implications for the development of the intervention and the choice of evaluation methods. Fourthly, I presented a ToC for the integration of mental health care in low and middle income countries. Fifthly, I demonstrated how ToC can be used as a framework for a qualitative comparative analysis of process and outcome data using longitudinal data from 10 PRIME implementation facilities in Nepal. Lastly, I provide a set of 10 key lessons learned from PRIME in the application of ToC to complex mental health interventions.

Results

I found that the ToC approach has been used for the design and evaluation of public health interventions since the 1990s. However, there is a lack of clear description of the use of ToC in the literature on public health interventions and inconsistency in how it is used. In applying the ToC approach to PRIME, I found that facilitators reported that ToC workshops were a valuable way to develop ToCs and that different stakeholders at the workshop contribute different types of information to the ToC process. Hierarchies within the health system are an important consideration for ToC workshops as power dynamics are likely to influence the functioning of the group.

In addition, I found that the development of a cross country ToC can result in a programme theory which is relevant for complex multilevel intervention in different contexts. This ToC can provide a framework to map contextually relevant interventions and can be used to complement other intervention development approaches. The ToC can also be used to

ensure indicators for all the short-, medium- and long-term outcomes are identified. However, combining process and outcome data analysis using the ToC is not straightforward. Qualitative Comparative Analysis (QCA) can be used to analyse process and outcome data in a single analysis in health services research.

Conclusion

ToC can be used to strengthen the design and evaluation of complex health interventions and can be used to complement the MRC guidance in the design and evaluation of complex health interventions.

Chapter 1. Introduction

1.1 Complex Health Interventions

Many health interventions are inherently complex. This complexity necessitates particular approaches to the design, evaluation and synthesis (Campbell, Murray et al. 2007, Shepperd, Lewin et al. 2009). As a result, the Medical Research Council, UK, published a revised guidance for *Developing and evaluating complex interventions* in 2008 (Medical Research Council 2008).

According to the revised MRC guidance (2008, pg. 7), complex health interventions are "conventionally defined as interventions with several interacting components". Dimensions of complexity include the number and variability of behaviours necessary to perform or receive the intervention, the organisations or organisational levels targeted by the intervention and the outcomes (Medical Research Council 2008).

However, others whose definitions follow from complexity theory differentiate between simple, complicated and complex interventions. For example, Rogers (2008) argues that complicated aspects of interventions include multiple locations and governance (often cross-jurisdictional and interdisciplinary), simultaneous causal strands or alternative causal strands, while complex aspects of interventions include recursive causality, non-linear effects and emergence of unexpected outcomes. Complex interventions include the same features as complicated interventions but are also characterised by feedback loops, learning and adaptation by those delivering and receiving the intervention, sensitivity to starting conditions and changing or re-prioritisation of outcomes. In this study, for the purposes of

consistency with the MRC framework, I will use the term complex health interventions to refer to both complicated and complex health interventions.

1.1.1 Challenges in the design and evaluation of Complex Health Interventions

Both the complicated and complex features of complex health interventions provide specific challenges for design and evaluation. Some of the challenges and methods suggested to address within the field of Evidence Based Medicine are described below.

Complex health interventions delivered at *multiple locations* need to be context sensitive as there can be large variations between locations. These include culture, language, and literacy, current financial and human resources within the health system as well as the broader organisational, political and social environment (Hawe, Shiell et al. 2004, Campbell, Murray et al. 2007). Approaches to the design of complex health interventions which improve sensitivity to context include using qualitative research methods during the design phase (Farquhar, Ewing et al. 2011) and standardising the complex health interventions and their components by process and function but not by form in a randomised controlled trial (RCT) (Hawe, Shiell et al. 2004). For example, an intervention to educate populations about depression (function) would require that all sites devise ways to distribute information tailored to local literacy, language, culture and learning styles rather than distributing the same written information kit (form). This is echoed by the MRC guidance that advises "ensuring strict fidelity to a protocol may be inappropriate" as "the intervention may work better if adaptation to local setting is allowed" (Medical Research Council 2008, pg. 7).

Multiple alternative or simultaneous causal strands make attribution of outcomes to a component of a complex health intervention difficult, and provide substantial challenges to the design and evaluation of complex health interventions. For this reason a thorough theoretical understanding of the causal pathways underlying the intervention is important during the design phase. This can be achieved through a rigorous understanding of the evidence base, developing an appropriate theory and modelling of potential outcomes (Campbell, Murray et al. 2007, Medical Research Council 2008).

Similarly, the evaluation of complex health interventions with multiple causal strands is difficult. Although RCTs are the most robust method for assessing effectiveness by using random allocation to intervention and control groups to distribute known and unknown confounders (Rychetnik, Frommer et al. 2002, Medical Research Council 2008), their reductionist approach often fails to differentiate between multiple causal strands (Ling 2012). The result is a *black box* evaluation, where one package of care made up of several components is compared to another alternative package of care without specifying the active ingredients (Linnan and Steckler 2002). Various approaches have been suggested to combat this including adding a process evaluation to randomised control trials using both qualitative and quantitative methods (Linnan and Steckler 2002, Oakley, Strange et al. 2006, Lewin, Glenton et al. 2009, Farquhar, Ewing et al. 2011), multiple case study approaches (Cohen, Eaton et al. 2011) or driver diagrams (Svoronos and Mate 2011).

Single or multiple causal strands may also lead to *multiple outcomes*. These outcomes should be articulated in the development of the theoretical model during the design phase of the complex health intervention and outcome measures chosen and refined prior to the evaluation (Medical Research Council 2008). The comparative importance of these should

also be considered when deciding on the statistical analysis of the outcome data and be based on both the theoretical relationship between the outcomes as well as the information needs of key stakeholders (Rychetnik, Frommer et al. 2002).

Unexpected outcomes may emerge given the complexity of the environments in which complex health interventions are implemented, as well as their inherent complexity. This can be mitigated by rigorous theory development and modelling. Evaluation design should include methods of detecting and reporting unintended outcomes (Rychetnik, Frommer et al. 2002, Medical Research Council 2008), for example, mixed methods design (Farquhar, Ewing et al. 2011) or process evaluation (Oakley, Strange et al. 2006).

The evaluation of complex health interventions which are *targeted at multiple organisational levels* need to evaluate all levels of action. This can be done through various methods such as a case study design (Cohen, Eaton et al. 2011), RCTs nested in facility level cohort studies or cluster randomised controlled trials. Cluster RCTs treat the highest level of intervention as the unit of analysis or cluster and randomise these to intervention groups. Outcomes can be measured at both the individual and the health facility or cluster level but the effect of cluster randomisation needs to be accounted for both in the design and analysis of the study (Ukoumunne, Gulliford et al. 1999). Randomisation of clusters may not always be feasible for various reasons such as ethical concerns or a small number of clusters leading to inadequate power.

When complex health interventions are *governed by multiple organisations* or levels there may be implications for the design of interventions. These could include difficulties in reaching consensus on the design of the complex health interventions and prioritising the

type of interventions. Different information needs across organisations may influence the choice of evaluation methods.

1.2 The MRC Guidance on Developing and Evaluating Complex Health Interventions

The MRC Guidance on Developing and Evaluating Complex Interventions was developed in the field of Evidence Based Medicine, developed to ensure that the practice of clinical medicine was evidence based. Evidence Based Medicine was influenced heavily by the experimental paradigms and therefore prioritised randomised controlled trials as the gold standard for testing interventions (Sackett, Rosenberg et al. 1996, Sehon and Stanley 2003). Interventions were traditionally medications or other discrete interventions which could be easily compared to placebo. Within this paradigm, the MRC guidance on complex health interventions (MRC 2000) was published, drawing heavily on the traditional pathway for pharmaceutical development (Dieppe 2006). It consisted of a linear framework of design and evaluation of complex health interventions (Medical Research Council 2000). These were divided into phases which are traditionally associated with the development of pharmaceuticals: Theory (Pre-clinical), Modelling (Phase I), Exploratory trial (Phase II), Definitive RCT (Phase III) and Long term implementation (Phase IV). These guidelines exclusively advocated the RCT to evaluate complex interventions and were criticised for lack of evidence supporting recommendations, poorly developed theory and modelling phases, very little guidance for the implementation phase, and a linear model (Dieppe 2006).

This was revised in 2008 to a more iterative four stage cyclical framework to guide the 1) development, 2) feasibility/piloting, 3) evaluation and 4) implementation of complex health intervention (Figure 1) (Medical Research Council 2008). Development includes the identification and synthesis of the evidence base, development of the theory underlying the intervention based on existing theoretical models and modelling the intervention. Feasibility/piloting refers to testing the intervention for acceptability as well as estimating relevant parameters for larger scale trials such as sample size and potential retention of subjects. Evaluation includes decisions on evaluation methods and outcome measures. Implementation refers to both approaches to increase the implementation of the research in the long-term, for example, including stakeholders in research; and long term surveillance.

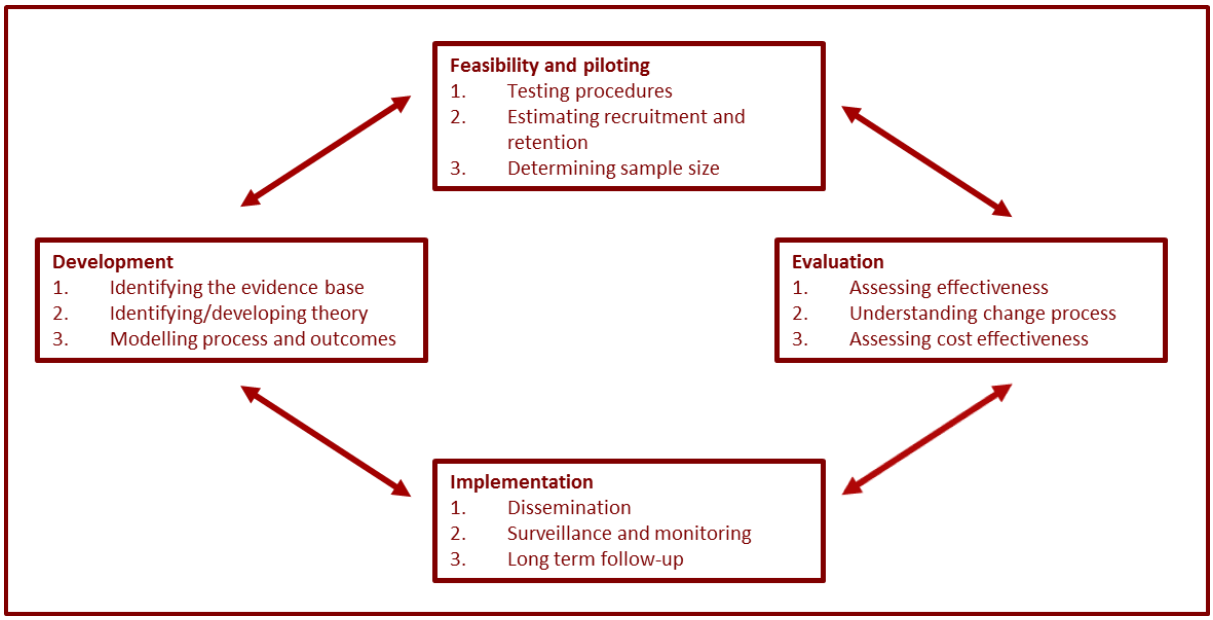

Figure 1-1 Four Stages of the Revised MRC Guidance (Craig, Dieppe et al. 2008)

The revised guidance still recommends RCTs as the most robust method to evaluate effectiveness, however, the authors concede that they may not be appropriate to all

research questions and contexts and give examples of alternative methods, for example, preference trials and natural experiments.

Mackenzie, O'Donnell et al. (2010) criticise the focus on RCTs in the revised guidance and argue that these are often not appropriate as complex interventions are inherently unstable and require reflexive learning. As a result, they may not become stable enough to be evaluated using RCTs. In addition, they criticise the narrow conceptualisation of context and suggest that context is integral to learning about how and why interventions are effective. Ling (2012) goes further and remarks that the revised guidance is "inherently unable to deal with complexity" because it "misses the point that interventions interact within complex systems in ways that cannot be predicted" (Ling 2012, pg. 80). He suggests that an approach which focuses on understanding the programme's underlying theory of change could enhance the evaluation of complex health interventions. This corresponds to criticism that the revised guidance does not explicitly acknowledge the potential of theory driven evaluation approaches, such as the Theory of Change (ToC) (Anderson 2008). Although the revised guidance provides a broad structure of how to approach evaluation of complex health intervention, it contains little practical guidance, especially with regard to theory development.

1.3 Theory Driven Evaluation

Theory driven evaluation falls within the domain of evaluation research which is the "systematic application of social research procedures in assessing the conceptualisation and design, implementation, and utility of social intervention program[me]s." (Rossi and Freeman 1985, pg. 19). Social programmes are usually interpreted broadly and refer to sets

of interventions or activities which lead to a defined outcome (US Department of Health and Human Services, Centres for Disease Conrol and Prevention et al. 2011) within or across several domains including education, health, criminal justice and development.

There are various theoretical approaches to evaluation. Alkin's *Evaluation Theory Tree* places the roots of evaluation in social inquiry, accountability and control and classifies evaluation theorists using three *branche*s: use, valuing and methods (Alkin 2004). The *use* branch refers to evaluation approaches that are mainly concerned with the way in which the results of evaluation are used. The focus is predominantly on generating information that will assist key programme decision making. Examples of approaches in the use branch include the CIPP (*context, input, process, product*) model (Stufflebeam 2005), discrepancy evaluation (Provus 1971), utilization-focused evaluation (Patton 2008), participatory evaluation (King 2005) and empowerment evaluation (Fetterman, Kaftarian et al. 1996). The *valuing* branch refers to the evaluators who believe that their role is to make a judgement on the value of what they are evaluating. Examples of these types of evaluation include Scriven's goal free valuation (Irvine 1979) and fourth generation evaluation (Guba and Lincoln 1989). The *methods* branch refers to evaluation approaches whose primary focus is the method of evaluation and how this produces knowledge. The methods branch includes experimental, quasi-experimental (Campbell and Stanley 1963) and theory driven approaches to evaluation (Chen 1990).

Theory driven evaluation approaches have historical roots in the work of Tyler in the 1930s (Coryn, Noakes et al. 2010) and Kirkpatrick in the late 1950s (Funnell and Rogers 2011). However, the "first boom period" (Funnell and Rogers 2011, pg. 19) of theory driven

evaluation occurred in the 1980s and was consolidated by the publication of Chen's *Theory Driven Evaluation.* In this book Chen criticises the prevalent "atheoretical approach to evaluation" which results in a "simple/input output or black box type of evaluation" (Chen 1990, pg. 18). Although he concedes that this approach may "provide a gross assessment of whether or not a programme works" it may "fail to identify the underlying causal mechanisms that generate the treatment effects". Since then, various approaches to theory driven evaluation have been proposed including the ToC approach (Weiss 1995) and Realistic Evaluation (Pawson and Tilley 1997). In recent years, theory-driven evaluation has been used and is required by many organisations in proposals and subsequent reporting including the World Bank, the Centres for Disease Control and Prevention, Australian Agency for Development, the Kellog Foundation and the United Kingdom's Department for International Development (DFID), (Coryn, Noakes et al. 2010, Funnell and Rogers 2011).

Theory-driven evaluation approaches posit that understanding the theory underlying a programme is necessary to understand whether, and how, a programme works (Coryn, Noakes et al. 2010). They have two key components: explicating a programme theory and seeking to investigate how programmes cause intended or observed outcomes (Coryn, Noakes et al. 2010). Common terms for Theory-driven evaluation approaches include programme-theory evaluation, theory based evaluation, theory guided evaluation, theory of action, theory of change, causal chain, causal pathway, mental model, impact planning, programme logic, logic models, logical frameworks, outcomes hierarchies and realist evaluation (Coryn, Noakes et al. 2010, Funnell and Rogers 2011).

1.4 Theory of Change

Within theory driven evaluation “theory of change” broadly refers to “central processes or drivers by which change comes about for individuals, groups or communities” (Funnell and Rogers 2011, pg. 34). However, Weiss (1995) and Connell and Kubisch (1998), as part of the Aspen Roundtable on Comprehensive Community Change, provided a more detailed guidance on 1) how to develop a theory of change (ToC); 2) how to use this to measure progress of a Comprehensive Community Initiative; and 3) how to analyse and interpret the results of the evaluation. As a result, ToC is often defined as a structured participatory approach to design and evaluation which provides "a systematic and cumulative study of the links between activities, outcomes, and contexts of the initiative" (Connell and Kubisch 1998, pg. 16). This is the definition I will use throughout this thesis.

The ToC approach uses a collaborative and collective approach to developing a theory of change. This is ideally achieved through a series of stakeholder workshops (Andersen 2004). The ToC is often represented graphically as a “ToC map” (Figure 1). Usually, in ToC workshops stakeholders first agree on the *impact* the programme should achieve. They then work backwards to identify the *preconditions* or *short-, medium-* and *long-term outcomes* required to achieve the impact. The evidence or *rationale* linking each step along the causal pathway is made explicit and *interventions* are added when necessary. *Assumptions* underlying the ToC are clearly articulated. Stakeholders also identify the *ceiling of accountability* after which the programme is no longer responsible for achieving the outcomes.

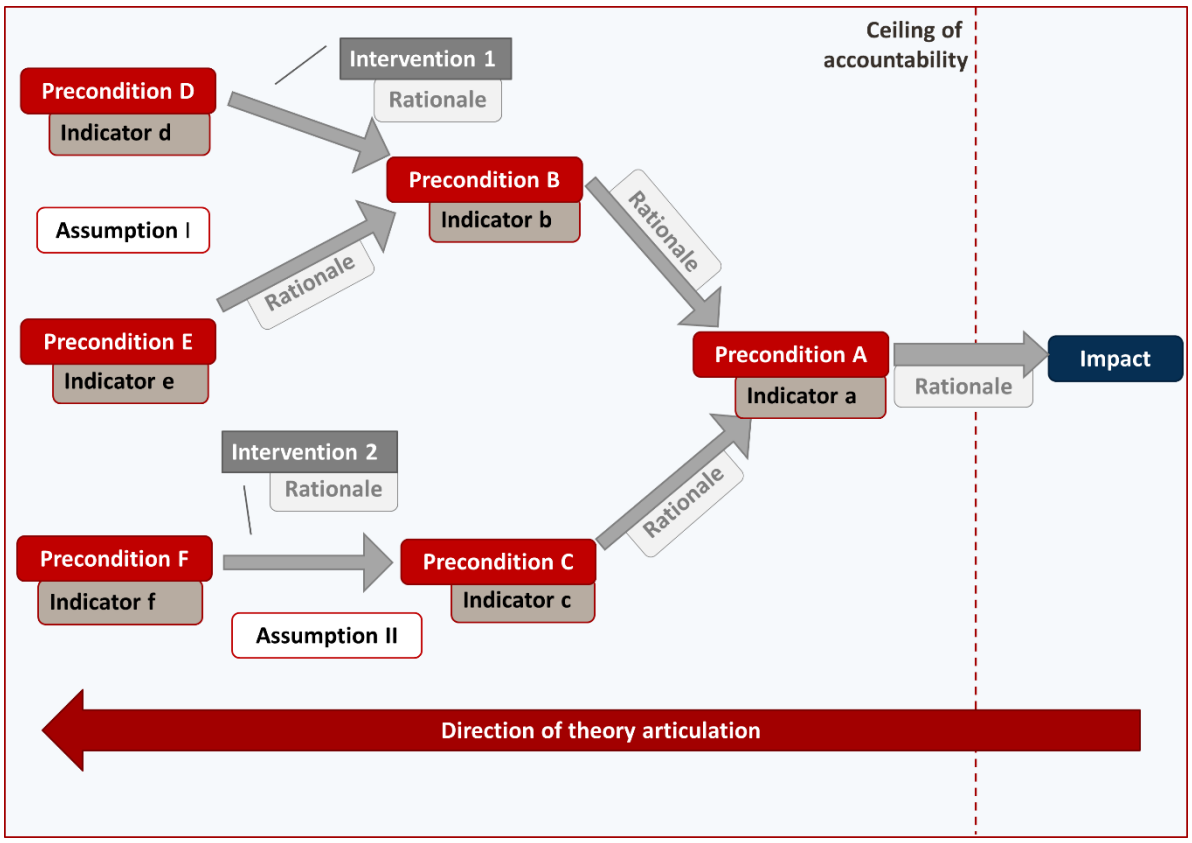

Figure 1-2 The structure of a theory of change map. Adapted from Andersen (2004)

Although the Aspen Roundtable on Comprehensive Community Change advocates that the development of the ToC is conducted in stakeholder workshops, they acknowledge it is "as fraught with difficulties as it is full of promise" (Connell and Kubisch 1998, pg.21, Andersen 2004). This has led to various methods of constructing ToC maps including individual interviews and focus groups (Mason and Barnes 2007). As a result of the development of the ToC, the ownership of the ToC map may not always rest with all key stakeholders, but with a small group of leaders, with the more dominant stakeholders or with the evaluator (Sullivan and Stewart 2006).

Once the ToC map has been constructed, it provides the framework both to implement the programme as a well as evaluate it. The ToC map identifies the activities and outcomes which should be measured, as well as the threshold required of these activities for the outcome to be achieved. In addition, it may provide a more rational structure for determining the appropriate times for measurement (Connell and Kubisch 1998).

Proponents of the ToC approach describe it as "method neutral" and therefore do not prescribe a specific method to evaluate the programme (Connell and Kubisch 1998). Instead, a suite of methods, often a mixture of qualitative and quantitative methods, is used where appropriate and integrated in the analysis (Granger 1998). However, structural equation modeling has been proposed as an analytic method for ToCs using non-experimental study designs (Adedokun, Childress et al. 2011).

ToC aims to unpack the "black box" of programmes by describing not only *whether* a programme works but also *how* and *why* (Connell and Kubisch 1998). It can assist with design and implementation of a programme, as well as determining the measurement and data collection methods. It links all aspects of the programme together and provides a way of integrating process and outcome measurement.

1.5 Other approaches to the development and evaluation of complex health interventions

In addition to the MRC Guidance on Complex Interventions and the Theory of Change approach, there are various fields of study and other approaches which are relevant to the development, implementation and evaluation of complex health interventions. I give some illustrative examples of these below and in Table 1.1.

The first, also from the field of Evidence Based Medicine, is the MRC Guidance on the Process Evaluation of Complex Health Interventions. Written as a companion the 2008 guidance on the development and evaluation of complex health interventions (Craig, Dieppe et al. 2008), this guidance published which focused the context, intervention description, implementation, and mechanisms of impact of complex health interventions (Moore, Audrey et al. 2015). As part of understanding of the mechanisms of impact of the intervention, Moore et al. advocates for the development of logic models.

Logic models have their historical roots in Theory Driven Evaluation, are conceptually similar to theories of change and are often used interchangeably (Funnell and Rogers 2011). However, the term logic model usually refers to the often linear visual representation of a programme theory and comprises of the inputs, activities, outputs and outcomes of a programme (Funnell and Rogers 2011). They key difference between logic models and ToC is

that the causal links between the activities, outputs and outcomes of the programme are often not explained (Wildschut 2014).

Implementation science theories, such as Normalisation Process Theory (May, Mair et al. 2009) (Murray, Treweek et al. 2010) or Organisational Readiness (Weiner 2009), often focus on the actual implementation process, the features of the intervention and context which facilitates more successful implementation of interventions.

Classic or grand theories, such as complexity theory, provide an abstract understanding of how individuals, systems or other entities interact. Complexity theory, for example, is a theory of how complex systems behave, adapt and co-evolve in a non-linear way. This has been applied in healthcare (Plsek and Greenhalgh 2001, Paina and Peters 2012). Complexity theory could be used to inform intervention development, for example, by monitoring scenarios and planning for unpredictability during implementation or to inform evaluation by ensuring unintended consequences are measured.

Frameworks like PREPARE-PROCEED (Crosby and Noar 2011) share many similarities with ToC. This includes framing the problem, assessing the situation in context and developing strategies for intervention. PREPARE-PROCEED also develops a programme theory and explicitly involve stakeholders in the development of the intervention. The evaluation strategy is then linked to the programme theory. However, PREPARE-PROCEED provides a detailed, step-wise approach to assessing context. This includes a detailed assessment of the social, epidemiological, behavioural, environmental, educational, ecological and policy contexts (Crosby and Noar 2011). These are then used to implement the intervention as well

as the process, impact and outcome evaluations. This structured approach to the assessment of context may be useful in ensuring all the elements of context are included. However, this structured approach is less flexible than ToC and may not be relevant to all programs.

Another public heath framework, RE-AIM (Glasgow and Estabrooks 2018) provides a framework for developing implementable programmes by asking explicitly about the reach, efficacy, adoption, implementation and maintenance of the programme. This approach focuses more on the implementation aspects of the programme in contrast to ToC which seeks to understand the causal mechanisms by which the programme will bring about change.

Table 1-1 Approaches relevant to design, implementation and evaluation of complex health interventions

Theoretical perspective	Theory/framework or model	Description
Evidence based healthcare	Revised MRC guidance on Evaluation of Complex Interventions (Medical Research Council 2008)	Four stage cyclical framework to guide the 1) development, 2) feasibility/piloting, 3) evaluation and 4) implementation of complex health intervention
	MRC guidance on process evaluation for complex interventions (Moore, Audrey et al. 2015)	Four domain framework to guide the process evaluation of complex health interventions: 1) context, 2) intervention description, 3) implementation, and 4) mechanisms of impact.
Theory Driven Evaluation approaches	Realistic evaluation (Pawson and Tilley 1997)	An evaluation approach derived from critical realism. The central tenet is that interventions have outcomes through a combination of context, actors and mechanism
	Logic model	A visual representation of a programme theory and usually comprises of the inputs, activities, outputs and outcomes of a programme (Funnell and Rogers 2011).
	Logframe	A matrix usually containing impacts, outcomes, outputs, inputs, assumptions/risks and indicators which is used for programme planning and evaluation (Wildschut 2014). Sometimes developed using a logical framework approach which explores the causal relationships between the key elements of the logframe
	Theory of Change	A programme theory which links activities, short-, medium- and long-term outcomes of a programme (Connell and Kubisch 1998)
Classic theories	Complexity Theory	A theory on how complex systems behave. Complex systems adapt, co-evolve in a non-linear way. This has been applied in healthcare (Plsek and Greenhalgh 2001, Paina and Peters 2012)

Theoretical perspective	Theory/framework or model	Description
Implementation Science	Conceptual model of diffusion of innovations (Greenhalgh, Robert et al. 2004)	A conceptual model which summarises the literature on diffusion innovations in service organisations. It includes the following domains: innovation and system antecedents and readiness for the intervention, communication and influence, outer contexts, linkages between the design and implementation stage, features of adoption/assimilation and the implementation process.
	Normalisation Process Theory (May, Mair et al. 2009) (Murray, Treweek et al. 2010)	A theory about the process of implementation which proposes that successful interventions need to be made routine within services to be embedded and sustained. Normalisation process theory proposes four mechanisms for complex interventions: coherence, cognitive participation, collective action and reflexive monitoring.
	Organisational readiness (Weiner 2009)	An organisational level implementation science theory which explains organisational level readiness as a function of organisational member's resolve and collective capacity to change.
	Integrated general theory of implementation (May 2013)	An implementation science theory which describes how implementation processes occur within social systems. May argues that contexts have dynamic elements (potential and capacity) and actors within this context have emergent expressions of agency (capability and contribution)
Evaluation frameworks	RE-AIM (Glasgow, Vogt et al. 1999)	A five element framework (reach, efficacy, adoption, implementation, maintenance) which aims to guide the development, evaluation and translation of research into practice.
	PRECEED-PROCEED (Green and Kreuter 1999)	A framework which outlines domains for the planning and evaluation of interventions

1.5.1 ToC as an adjunct to the MRC framework

Complex health interventions share many of the features of complex community initiatives that make them hard to evaluate. These include working at multiple horizontal and vertical levels, dependence on context, flexibility, evolving interventions and a broad range of outcomes (Weiss 1995). In 2014, De Silva, together with me and other colleagues, proposed that using a ToC approach to evaluate complex health intervention may strengthen all four stages of the MRC framework, namely the intervention development, feasibility/piloting, evaluation and the implementation stages (De Silva, Breuer et al. 2014). I summarise our proposal in the following four paragraphs.

The MRC guidance recommends that explicit theory is used in the *intervention development* stage in order to better design complex health interventions and their evaluations (Medical Research Council 2008). We posited that the ToC approach may provide a structure to this theory development in the form of stakeholder workshops and a backward mapping approach (De Silva, Breuer et al. 2014). The backward mapping approach shifts the focus towards the outcomes which need to be achieved rather than on the content of the proposed complex health intervention. This allows an alternative approach to thinking about the necessary outcomes as well as potentially novel ways to achieve them.

The co-construction of the ToC through workshops may create a sense of ownership and buy-in for key stakeholders, including those who will be directly involved with implementation. In addition, stakeholders can provide rich contextual understanding of the

health system and community in which the complex health intervention will need to function and recommend changes to the intervention to improve the chances that the complex health intervention may become part of routine practice (Murray, Treweek et al. 2010). It also compels stakeholders to reach consensus and prioritise outcomes within resource constraints (De Silva, Breuer et al. 2014), which could be further informed by prospective economic or mathematical modeling based on the ToC map. In addition, if indicators and levels of success are co-constructed with stakeholders, they may find them more relevant and may be more likely to accept the results of the evaluation as attributable to the complex health intervention.

The MRC guidance recognises that the *feasibility/piloting* stage may resolve problems such as acceptability, compliance and delivery of the intervention (Medical Research Council 2008). Working with stakeholders to explicate the assumptions underlying the ToC may identify modifiable barriers to acceptability and compliance as well as the practical difficulties in implementation. The articulation of the rationale for linking outcomes and underlying proposed interventions on the ToC map can highlight the gaps in knowledge, which can be filled either through literature reviews or formative research (De Silva, Breuer et al. 2014). The ToC process may also identify where small-scale pilots are necessary to contextualize and refine specific components of the complex health intervention.

The ToC approach can be a key adjunct in the *evaluation* stage of the MRC guidance. It provides an overall evaluation framework from which key research questions and outcomes for each component of the ToC can be identified which can be answered using mixed methods. De Silva, Breuer et al. (2014) suggest that this evaluation framework allows early

identification of implementation failure by providing process information for each component. As the process and outcome evaluations are guided by the same framework, they can be evaluated together providing a detailed map of how and why the intervention did or did not achieve its outcome (De Silva, Breuer et al. 2014, De Silva, Breuer et al. 2014). The MRC guidance highlights that study designs should be chosen according to the situation, with a thorough understanding of processes that should be in place and a consideration that multiple outcomes may be necessary to evaluate the complex health intervention (Medical Research Council 2008).

Various strategies are suggested by the MRC guidance in order to improve *implementation* of the complex health intervention, including involving stakeholders in determining the research question and the design of the research, taking into account the context and long term monitoring and surveillance (Medical Research Council 2008). In the ToC approach, stakeholders are involved from the beginning and agree on final outcomes, and the pre-conditions and interventions needed to achieve this. The input of stakeholders ensures that the complex health intervention is context specific. The buy-in of stakeholders is likely to assist with adoption of the intervention, as these stakeholders will probably be involved in implementing the intervention. The ToC may also provide a framework to identify key indicators which could provide long term follow up and surveillance (De Silva, Breuer et al. 2014).

1.6 Applying theory of change to the integration of mental health care into routine health services

ToC has been used to develop and evaluate complex community initiatives such as the Health Action Zones (Barnes, Matka et al. 2003, Cole 2003, Sullivan, Judge et al. 2004, Bauld, Judge et al. 2005, Sullivan, Barnes et al. 2006), New Deal for Communities (Sullivan and Stewart 2006) and Local Strategic Partnerships in the United Kingdom (Sullivan and Stewart 2006). Many of the theoretical aspects of these evaluations have been discussed in the programme evaluation literature. However, there have been few detailed examples of how to develop and evaluate interventions with ToC. In a systematic review by Coryn, Noakes et al. (2010), of the 45 examples of theory driven evaluation, only 21 were evaluations of public health interventions and three used ToC specifically. None made reference to the revised MRC guidance.

The revised MRC guidance provides an overarching framework for the design and evaluation of complex health interventions but does not provide adequate practical guidance. It has been criticised for not including theory driven approaches to evaluation such as ToC (Anderson 2008).

At the time of the conceptualization of this thesis, the ToC approach had not been used to develop and evaluate complex mental health interventions in low- and middle-income countries (LMIC). ToC is particularly suited to mental health interventions as they are inherently complex. Domains of complexity include 1) simultaneous interventions, for example, psychological, pharmacological, economic and social; 2) different levels of care, for

example, both primary and specialist care; and 3) different service providers, such as non-governmental organisations (NGOs) or other government departments.

This thesis proposes to fill the knowledge gap on the application of a ToC approach in conjunction with the MRC framework for the development and evaluation of complex mental health interventions in low and middle-income countries (LMIC). I will use the example of the Programme for Improving Mental Health Care (PRIME). PRIME is a research programme consortium that aimed to integrate mental health services into primary healthcare by implementing and evaluating complex mental health interventions in Ethiopia, India, Nepal, South Africa and Uganda. In order to provide the context for the research, I briefly outline the need for the integration of mental health services into primary healthcare and then introduce PRIME. This is followed by the aims and objectives of the thesis.

1.6.1 The need for integration of mental health into routine health services

Around, 35.5% to 50.3% of people with severe mental illness in high-income countries and 76.3% to 85.4% in LMIC do not receive evidence-based treatment (Demyttenaere, Bruffaerts et al. 2004). This is despite a substantial burden of disease: in 2010, mental, neurological and substance use disorders accounted for 10.4% of disability adjusted life years and 28.5% of years lived with disability globally (Whiteford, Ferrari et al. 2015).

Part of the reason for lack of access to treatment is the historical separation of physical and mental health services and the location of mental health care in specialist psychiatric

hospitals. From the 1950s, a process of deinstitutionalisation started in England, USA and Europe where mental health services became increasingly community based (Novella 2010). However, in many LMIC, mental health services are still predominantly provided in specialist hospitals with only 52% of low income countries providing care by health or social workers outside the hospital (Saxena, Thornicroft et al. 2007). In contrast, 97% of high-income countries provide this type of care. As a result, mental healthcare in LMIC is often scarce, inaccessible, expensive and perpetuates mental health stigma and human rights abuses (World Health Organization and World Organization of Family Doctors 2008). In response to this low access to treatment and lack of available services, interest in the field of global mental health is growing. Global mental health has been defined as "an area for study, research and practice that places a priority on improving [mental] health and achieving equity in [mental] health for all people worldwide" (Patel and Prince 2010).

Global mental health researchers, together with the World Health Organisation (WHO), have called for the integration of mental health services into routine health care in order to 1) improve access to services (Collins, Insel et al. 2013, Saxena, Funk et al. 2013); 2) improve efficiency within health services (Chisholm and Saxena 2012); 3) provide additional opportunities for detection and treatment of co-morbid physical and mental illness (Collins, Insel et al. 2013); and 4) reduce stigma (Patel, Belkin et al. 2013).

However, the integration of mental health into routine services remains challenging for several reasons. Stigma may still be present in primary clinics amongst patients and service providers (Henderson, Noblett et al. 2014, Li, Li et al. 2014). Continuity of care may be difficult in busy primary care settings where staff turnover is often high (Patel, Belkin et al.

2013). Specialist service providers (psychiatric nurses, psychiatrists, psychologists) who are essential for supervision and training may not be available (Kakuma, Minas et al. 2011). Additional resources may be needed in primary care clinics, especially in low resource primary care systems which are already under strain. And finally, a lack of allocated mental health budget means that this may not be possible (Saxena, Thornicroft et al. 2007, Kakuma, Minas et al. 2011, World Health Organization 2011).

An example is Nepal, a low-income country in South Asia. Luitel, Jordans et al. (2015) conducted a recent situational analysis and found that specialist mental health services were limited and concentrated at district and zonal hospitals. Although provision of mental healthcare is part of the mandate of primary health services, there is no evidence that they are being provided routinely and where individuals have been trained service provision is hampered by lack of ongoing supervision, refresher training and medication supply. This is compounded by lack of district level mental health planning and poor health information systems (Upadhaya, Jordans et al. 2017).

Thornicroft and Tansella, based on review of the evidence and a survey of 170 experts, recommend three different models of a mental health system depending on the resources available. In a low resource setting, a mental health system should include case finding and assessment, psychosocial and pharmacological interventions with specialist support for training and supervision consultation for complex cases, in and outpatient assessment and treatment for those who cannot be managed at primary care. Middle resource settings should include mental health services at primary care but add general adult mental health services which include community mental health teams, long term residential care and work

and occupational assistance. High income settings should include the same as middle resource settings but add specialist mental health services in addition to general health services (Thornicroft and Tansella 2013).

1.6.2 The Programme for Improving Mental Health Care as a complex mental health intervention

Despite the increasing calls for the integration of mental health into routine health services, there is little evidence of how this can be done at district level in LMIC (Dua, Barbui et al. 2011). PRIME is a Department for International Development (DFID) funded project which aimed to generate this evidence by developing, implementing, evaluating and scaling up district specific mental healthcare plans (MHCPs) in LMIC (Lund, Tomlinson et al. 2012). PRIME is led from the University of Cape Town and is a partnership between local academic institutions, non-governmental organisations and Ministries of Health in Ethiopia, India, Nepal, South Africa and Uganda, and other partners such as the WHO and Centre for Global Mental Health in London. The PRIME implementation countries have a range of diverse characteristics including geographic area (Sub-Saharan Africa and South Asia), income level (low to upper middle income), political stability, governance, and mental health service resources. The mental disorders which PRIME has focussed on have been determined by consideration of burden of disease, availability of evidence based interventions and political priorities, and include depression, alcohol use disorders, psychosis and in Ethiopia, Nepal and Uganda, epilepsy (Lund, Tomlinson et al. 2012).

The research presented in this thesis was conducted as part of the first two phases of the Programme for Improving Mental Health Care (PRIME) in nominated districts or sub-districts in PRIME countries, namely Sodo, Ethiopia; Sehore, India; Chitwan, Nepal; Dr Kenneth Kaunda, South Africa; and Kamuli, Uganda. During the *inception phase* of PRIME (2011-2013), district specific integrated mental healthcare plans (MHCPs) were developed and subsequently implemented and evaluated in the *implementation phase* of the project (2013 – 2016). This study investigated how the addition of a ToC approach influenced the design and evaluation of the PRIME MHCPs.

The PRIME MHCPs comprised of *packages* of care made up of several *components* targeted at three *levels* of the health care system, namely healthcare organisation, health facility and community. Each level included *domains* of awareness, detection, treatment, recovery and enabling. For example, at the healthcare organisation level the packages included awareness raising for district stakeholders and packages enabling medication supply, programme management and health information systems. At the facility level there were packages related to the involvement of specialist services in the treatment, for example of complex cases, recovery and enabling domains and in primary care across all domains. At community level, there were packages across all domains. The MHCPs differed in each country but the core components across countries can be seen in Figure 1.3. For a detailed comparison across countries refer to Hanlon, Fekadu et al. (2016).

The PRIME MHCPs contain elements of both complicated and complex interventions as outlined by Rogers (2008). PRIME was implemented by *multiple agencies* in each of the five countries through collaboration between a PRIME academic or NGO country partner and the Ministry of Health at the state or national level. PRIME MHCPs were implemented in

multiple locations at *multiple levels* (health organisation, health facilities and specialist services and communities).

PRIME MHCPs have *multiple alternative* and *simultaneous causal strands*. For example, community awareness campaigns to increase attendance at the health facility where training and supervision aimed to increase detection and treatment of those with priority disorders. This treatment may include psychological, pharmacological, family support or livelihoods interventions which may lead to better health, social and economic outcomes.

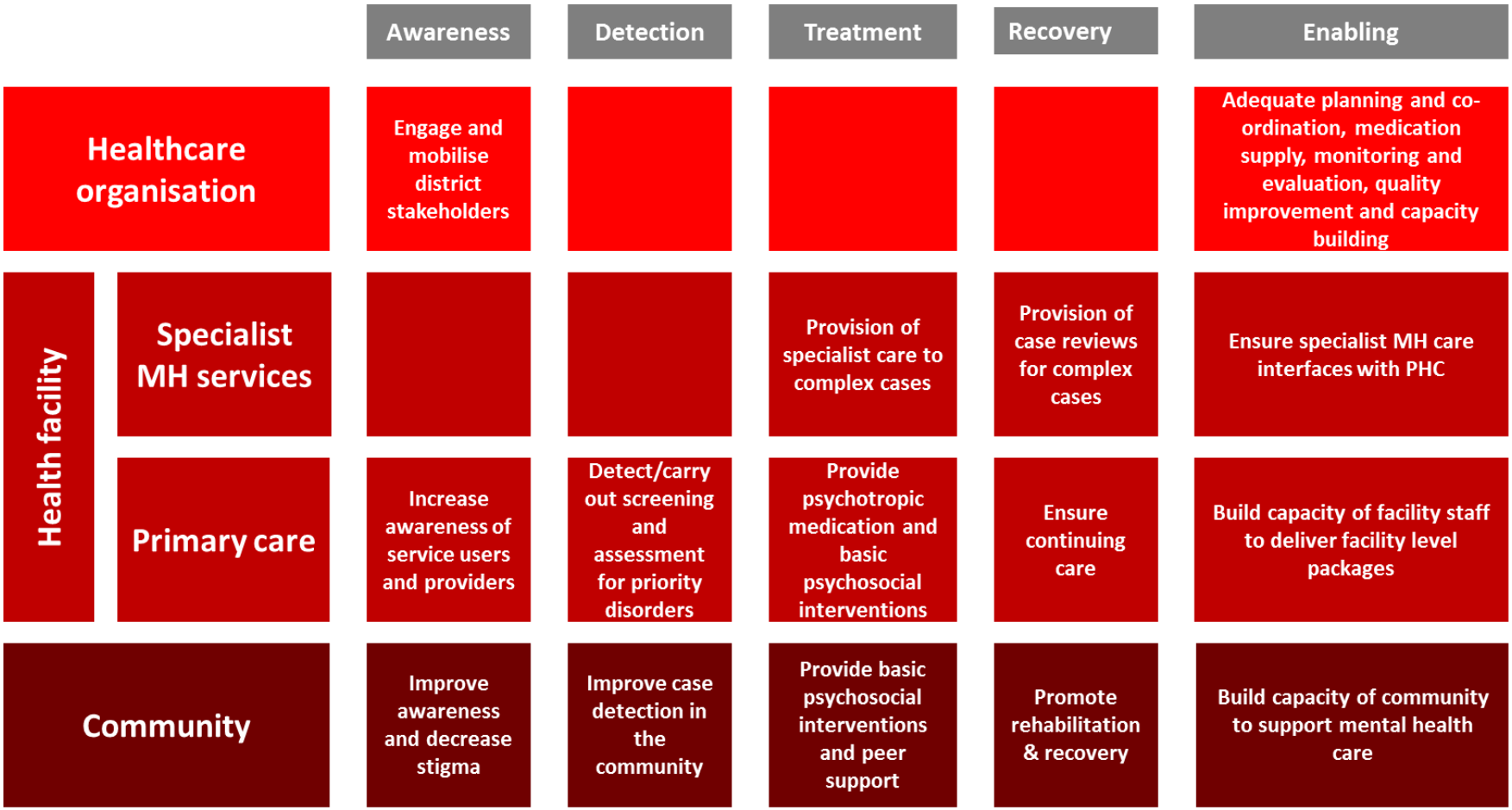

Figure 1-3 Components of the PRIME Mental Health Care Plans. For more detail refer to Hanlon et al. (2014)

Given that PRIME is a complex adaptive intervention integrated into an existing complex health system (Plsek and Greenhalgh 2001) it is likely that *unexpected outcomes* would emerge and that there would be aspects of *recursive causality* and *non-linear change*.

This complexity results in challenges for both the design and evaluation, which the ToC approach may help to mitigate. As outlined above, ToC may provide an overall theoretical framework for evaluation which incorporates formative, process and outcome evaluation (De Silva, Breuer et al. 2014). This framework can be co-constructed with stakeholders during ToC workshops which may increase buy in and adaptation of the complex health intervention to the context. This study will determine the value of the ToC approach in the development and evaluation of the PRIME MHCPs, as an example of complex mental health interventions.

1.7 Aims and Objectives

The aim of this research is to critically appraise how ToC can be used as a comprehensive approach to guide the design and evaluation of the PRIME Mental Health Care Plans.

The objectives of the research are to:

1) Explore and critically evaluate the literature on ToC and its use in the design, implementation and evaluation of complex health interventions.
2) Describe and compare the process of conducting ToC workshops to design complex mental health interventions in five LMICs.
3) Critically evaluate the role and value of a ToC approach in designing and evaluating complex mental health interventions in five LMICs.
4) Present and describe a ToC for the integration of mental health into primary healthcare
5) Conduct an integrated analysis of the process and outcome indicators of complex mental health interventions and test the causal pathways outlined in the PRIME ToC using data from Nepal.
6) Write a commentary reflecting on the use of ToC in the design and evaluation of complex healthcare interventions.

1.2 Clarifying the role of Theory

This thesis is primarily methodological and has conceptual roots in the field of Evidence Based Medicine. It draws its theoretical framework from the Revised MRC Guidance on Complex Interventions (Craig, Dieppe et al. 2008) which is described in detail in Section

1.2. This thesis contributes to the increasing debate and body of knowledge on the inclusion of programme specific theories in the design, implementation and evaluation of complex health interventions

The revised MRC Guidance has since become more nuanced than its predecessor (MRC 2000) , calling for modelling of interventions but providing no guidance on how this could be operationalised. Moore and colleagues (2015) in the subsequent MRC Guidance for Process Evaluations call for theory informed process evaluation (Moore, Audrey et al. 2015). Moore and Evans (2017) expand on this in another paper to caution against using "off-the-shelf" theories but rather to develop programme specific theories of change which incorporate context. They also argue for the importance of including local stakeholders in the co-production of these theories. This is echoed by Hawe (2015) who advocates for the *a priori* development and peer review of programme theories to determine whether the interventions are likely to result in the changes anticipated by the programme. In the emerging and related field of Implementation Science, Van Belle, van de Pas et al. (2017) argue that research that develops middle range theories is even more valuable than theory-based research in order to build upon knowledge from one programme to the next. Middle range theories are theories that are neither the working hypothesis of a programme, nor a grand unifying theory. Middle range theories can incorporate and draw on grand unifying social science and other theories in their development. Programme theories then operationalize and test middle range theories. The relationship between grand, middle range and programme theories is outlined in Figure 1.4.

Figure 1-4 Grand, middle range and programme theories. Adapted from Shearn, Allmark et al. (2017)

This thesis makes a methodological contribution to knowledge by showing how a programme specific ToC can be developed in a participatory way across multiple settings and used to develop and evaluate complex health interventions. It aims to provide a worked example of how this ToC can be evaluated using Qualitative Comparative Analysis. In addition, it aims to provide a starting point for middle range theory for integration of mental healthcare in primary healthcare which can be developed, adapted and expanded upon in further research.

1.3 Overview of chapters

This thesis is divided into seven chapters. In the introduction, I introduce the concepts of complex interventions, ToC and the case for the integration of mental health into primary healthcare. I describe the PRIME project as a complex health intervention and argue for how ToC might assist with the design and evaluation. Lastly, I outline the aims and objectives of

the thesis, clarify the role of theory, outline the chapters of the thesis and my contribution to each chapter.

In Chapter Two, I present a systematic review which I conducted in order to explore and critically evaluate the literature on ToC and its use in the design, implementation and evaluation of complex health interventions. The idea to conduct this study was mine. I developed the protocol which was reviewed by my supervisors, Prof Crick Lund and Dr Mary De Silva, and my co-author Ms Lucy Lee. Ms Lee and I double screened all the abstracts and the full text articles against the inclusion and exclusion criteria. I conducted the data extraction and analysis and wrote the first draft of the paper. All authors reviewed and gave input into the final manuscript prior to publication. The paper has been published in Implementation Science (Breuer, Lee et al. 2016).

In Chapter Three, I describe and compare the process of conducting ToC workshops to design complex mental health interventions and critically evaluate the role and value for the development of ToC across the five PRIME countries. The study was conceptualised by myself under the guidance of my supervisors, Prof Crick Lund and Dr Mary De Silva. A/Prof Abebaw Fekadu, Prof Inge Petersen, Dr Juliet Nakku, Mr Vaibhav Murhar and Mr Nagendra Luitel conducted the ToC workshops in PRIME countries together with other members of the PRIME consortium and contributed to the collection of process documentation. I conducted the interviews and data analysis and drafted the manuscript under the guidance of my supervisors. All other authors were involved in critically revising the manuscript and all authors approved the final draft before publication. This paper has been published in the International Journal of Mental Health Systems (Breuer, De Silva et al. 2014).

In Chapter Four, I describe the overall ToC approach taken in PRIME, and present the resultant ToC. The paper was conceptualised by myself under the guidance of my supervisors, Prof Crick Lund and Dr Mary De Silva. The PRIME ToC was developed as part of the work of the PRIME consortium. The process was led by myself with guidance and input from Dr Mary De Silva. Dr Rahul Shidhaye, Prof Inge Petersen, Dr Juliet Nakku, Dr Mark Jordans and A/Prof Abebaw Fekadu contributed to the development of the cross county ToC and oversaw the development of ToC in their countries. I wrote the first draft of the paper and all authors were involved in critically reviewing the manuscript prior to publication. The paper has been published in a supplement to the British Journal of Psychiatry (Breuer, De Silva et al. 2016).

In Chapter Five, I show how Qualitative Comparative Analysis (QCA) can be used together with ToC to conduct an integrated analysis of the process and outcome indicators of complex mental health interventions and test the causal pathways outlined in the PRIME ToC. QCA is a social science approach which has not, to my knowledge, been used together with ToC. I developed the idea for this study under the guidance of my supervisors Dr Mary De Silva and Prof Crick Lund, and Prof Bruno Marchal. The data were collected as part of the PRIME consortium evaluation in Nepal led by Dr Mark Jordans and Mr Nagendra Luitel. Ms Prasansa Subba, Mr Nagendra Luitel and Dr Mark Jordans assisted with the interpretation of the data and gave information about the context. I undertook a novel application of QCA with ToC, conducted the analysis and wrote the first draft of the paper. All authors reviewed the manuscript prior to submission. This paper is under review at BMJ Global Health.

In Chapter Six, I provide a commentary about the ten key lessons from how ToC was used in the design, implementation and evaluation of PRIME, for the purpose of informing future complex mental healthcare interventions. I have written this paper based on the experience of using the ToC approach within PRIME under the supervision of my supervisors, Dr Mary De Silva and Prof Crick Lund. Both supervisors reviewed the paper prior to publication. The paper is under review at Global Mental Health.

In the concluding Chapter Seven, I start by highlighting the key findings of the thesis and how they have contributed to the literature on complex interventions. I then present the theoretical contributions, role of context, implications for policy and practice, limitations and recommendations for further research.

Chapter 2. The use of Theory of Change to design and evaluate Public Health Interventions: a systematic review

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Minor changes have been made to the published paper in response to comments from the examiners

2.1 Abstract

2.1.1 Background

Despite the increasing popularity of the Theory of Change (ToC) approach, little is known about the extent to which ToC has been used in the design and evaluation of public health interventions. This review aims to determine how ToCs have been developed and used in the development and evaluation of public health interventions globally.

2.1.2 Methods

We searched for "theory of change" used for the development or evaluation of public health interventions in databases of peer reviewed journal articles such as Scopus, Pubmed, PsychInfo, grey literature databases, Google and websites of development funders. We included papers of any date, language or study design. Both abstracts and full text articles were double screened. Data were extracted and narratively and quantitatively summarised.

2.1.3 Results

A total of 62 papers were included in the review. Forty-nine (79%) described the development of ToC, 18 (29%) described the use of ToC in the development of the intervention and 49 (79%) described the use of ToC in the evaluation of the intervention.

Although a large number of papers were included in the review, the descriptions of the ToC development and use in intervention design and evaluation lacked detail.

2.1.4 Conclusions

Use of the ToC approach is widespread in the public health literature. Clear reporting of the ToC process and outputs are important to strengthen the body of literature on practical application of ToC in order to develop our understanding of the benefits and advantages of using ToC. We also propose a checklist for reporting on the use of ToC to ensure transparent reporting and recommend that our checklist is used and refined by authors reporting the ToC approach.

2.2 Background

Most public health interventions (PHIs), are inherently complex, with multiple interacting components, delivered at multiple levels. This complexity makes them difficult to evaluate using traditional experimental designs. PHIs often rely on ongoing quality improvement based on the implementation experience. Therefore they may not reach the level of stability required to conduct evaluations such as randomised controlled trials (RCTs) (Mackenzie, O'Donnell et al. 2010). Some researchers propose that understanding the PHI's underlying theory of change and its related uncertainties may improve the evaluation of complex health interventions (Mackenzie, O'Donnell et al. 2010, Ling 2012, De Silva, Breuer et al. 2014).

The ToC is usually developed in consultation with stakeholders through workshops or interviews although the participation of stakeholders can vary substantially in practice (Sullivan and Stewart 2006). For example, some ToCs are developed through a series of workshops and meetings with a wide range of stakeholders including service users (Hernandez and Hodges 2006, Breuer, De Silva et al. 2014). Theory driven evaluation is a collection of evaluation methods which emphasise the importance of understanding how and why a programme works in order to evaluate it (Coryn, Noakes et al. 2010, Funnell and Rogers 2011). By programme, we mean a set of organised activities or intervention supported by resources which intend to achieve a specific result (US Department of Health and Human Services, Centres for Disease Conrol and Prevention et al. 2011). The theories are first made explicit and then used to see how the programme theory results in the intended outcomes (Coryn, Noakes et al. 2010). There are several overlapping types of

theory driven evaluation approaches including logic models, logical frameworks, outcomes hierarchies, realist evaluation and theory of change (ToC) (Coryn, Noakes et al. 2010, Funnell and Rogers 2011).

ToC was developed by Weiss and others (1995) within the tradition of theory driven evaluation. Although definitions of Theory of Change (ToC) vary, we define it as an outcomes-based approach which describes how an intervention brings about specific outcomes through a logical sequence of intermediate outcomes (Vogel 2012). The ToC is often developed using a backward mapping approach which starts with the *long term outcome* and then maps the required *process of change* and the short and medium term outcomes required to achieve this (Andersen 2004). During this process the *assumptions* about what needs to be in place for the ToC to occur are made explicit as well as the *contextual* factors which influence the ToC. Additional elements of a ToC can include *beneficiaries, research evidence supporting the ToC, actors in the context, sphere of influence, strategic choices and interventions, timelines* and *indicators* (Vogel 2012). These elements are usually presented in a diagram and/or narrative summary (Vogel 2012) whereas others are developed by evaluators and funders using programme documentation (Weitzman, Silver et al. 2002, Knowlton and Phillips 2012). The resulting ToCs can be used as a framework for programme development and evaluation (Vogel 2012). The ToC approach is method neutral and as such does not prescribe specific types of evaluation methods (Connell and Kubisch 1998).

ToC is distinct from sociological or psychological theories which describe why change occurs although these may be used to inform the ToC (De Silva, Breuer et al. 2014). For example,

Bauer used ecological model of community organising to inform a ToC for a capacity and advocacy initiative for residents to impact on public health policy and training of public health professionals (Bauer 1999).

ToC differs from other theory driven approaches to evaluation despite similar origins. For example, although logic models outline the inputs, processes, outputs and outcomes of a programme in a similar manner to ToC, they can be rigid and do not make explicit the causal pathways through which change happens in the way that ToC does (De Silva, Breuer et al. 2014). Although logframes were initially developed to summarise discussions with stakeholders, funder driven formats have largely reduced logframes to a results based management tool (Prinsen and Nijhof 2015). Realist evaluation, on the other hand, comes from a perspective of scientific realism and focuses predominantly on the interaction between the context, mechanisms and outcomes of the programme. Usually used post-hoc, evaluators seek to uncover the underlying programme theories. These theories are often more abstract than the theories developed through ToC or logic models (Marchal, van Belle et al. 2012). The development of ToC has been influenced by the Freirean thinking on how to create social change by empowering individuals (James 2011). Despite some fundamental differences in their theoretical underpinnings many of these approaches are used interchangeably or together (Blamey and Mackenzie 2007, Marchal, van Belle et al. 2012).

ToC has been used widely in the development sector for programme development and evaluation by funders such as the UK's Department for International Development, Comic Relief, Grand Challenges Canada and the Gates Foundation (James 2011, De Silva, Breuer et al. 2014). However, there has been no global systematic review to our knowledge on the

use of ToC in public health interventions. Coryn, Noakes et al. (2011) conducted a review of theory driven evaluation more broadly. They found 45 examples of theory driven evaluation in the peer reviewed literature between 1990 and 2009. These evaluations included education, crime and safety, and transportation interventions, with roughly half (21/45) evaluations of health interventions (Coryn, Noakes et al. 2011). A rapid analysis of the included papers in preparation for this review indicated that only three of these used ToC.

The lack of a systematic reviews means that there is no clear idea of the how ToC has been used and reported on in the peer-reviewed and grey literature a on in relation to PHIs. Given the increasing popularity of the ToC approach, understanding how it is has been used and described previously allows future users of the approach to learn from the work of other and build upon it. It also helps to move towards a more consistent ways of using the ToC approach.

In this review, we sought to review both peer-reviewed and grey literature to determine how ToCs have been developed and used in the development and evaluation of public health interventions globally. Specifically, we sought to answer the following questions:

1. How are ToCs for public health interventions developed and refined?
2. How is the ToC approach used in the
    a. Development of an intervention;
    b. Implementation of the intervention;

c. Evaluation of the intervention, including statistical approaches and the development of indicators for measurement; and
d. Conceptualisation/evaluation of influence of context.

2.3 Methods

The authors developed a protocol for this review which was agreed prior to the commencement of the study. This is available in Appendix 2.1. The PRISMA guidelines for reporting systematic reviews were followed (Moher, Liberati et al. 2009).

2.3.1 Inclusion and Exclusion Criteria

The inclusion and exclusion criteria are listed in Box 2.1. In summary, we included studies of public health interventions which were defined as interventions which are intended to protect health or prevent or treat ill health in communities or populations (Rychetnik, Frommer et al. 2002). We included interventions addressing any health issue in all populations which described how a ToC approach to design, implement or evaluate a public health intervention, or that described the development of a ToC for a public health intervention. We required papers to specifically mention that they used "theory of change" and excluded those who did not for the following reasons. Firstly, as described above, there are a range of overlapping definitions for ToC and other programme evaluation methods. Given the often minimal amount of detail provided about the programme theory in articles, and especially in abstracts, it would be difficult to enforce a standard criteria for ToC against

which papers could be evaluated for inclusion. Secondly, piloting the initial broad search strategy (including all synonyms for ToC and programme logic) returned more than 20,000 hits in only three databases. By refining this criteria to specify ToC by name, we were able to thoroughly explore literature which explicitly self-identified using ToC.

We included all studies describing how a ToC was developed for a public health intervention or how a public health intervention was developed or evaluated. Evaluation study designs included longitudinal studies, quantitative surveys, case study research (Yin 2009) and qualitative studies. We excluded reviews and methodological or advocacy papers unless they included an example of how a ToC was developed or how ToC was used in the design, evaluation and/or implementation of a public health intervention. We did not limit the inclusion by date, language, study design or type of publication.

Box 2.1 Inclusion and exclusion criteria

Inclusion criteria:

- Describes or evaluates a public health intervention defined as any interventions which are intended to protect health or prevent ill health in communities or populations (Rychetnik, Frommer et al. 2002)
- Self-identifies as using a ToC approach and specifically mentions "theory of change"
- Describes how a ToC was developed or how ToC was used in the design, evaluation and/or implementation of a public health intervention.
- Any date
- Any language
- Any country

Exclusion criteria:

- Conceptual/methodological or advocacy papers unless they include an example of how a ToC was developed or how ToC was used in the design, evaluation and/or implementation of a public health intervention
- Review articles
- Specific psychological, sociological or organisational theory (unless used to inform the ToC)
- ToC in which the outcome is a change within an individual rather than change at population level. For example, a theory of how cognitive behavioural therapy may impact on an individual's cognitive processes and behaviour would be a change within the individual but if the focus of the ToC was on how a cognitive behavioural therapy intervention impacts the prevalence of depression it would be change at a population level.

2.3.2 Screening and eligibility

Following the search of databases of peer reviewed journal articles, the titles and abstracts of the search results from peer reviewed papers were exported into Endnote (Endnote 2015) where duplicates and irrelevant titles were removed. The peer-reviewed journal articles found through contact with experts were added to this. The titles and abstracts were double screened by EB and LL against the inclusion and exclusion criteria. Once the abstracts were screened, the full papers or reports of the included abstracts were obtained and assessed for eligibility by both reviewers.

Following the grey literature search as described above, all potentially relevant results were saved into Evernote (Evernote Cooperation 2015). These were double screened by both reviewers against the inclusion and exclusion criteria. Any differences between authors' opinions were resolved via discussion throughout the review process.

2.3.3 Data extraction and analysis

The data from the content of the paper were extracted by the first author (EB) onto a data extraction form. This included information on authors, publication dates, the type of interventions and outcomes, the development of ToC, the use of ToC in the design, implementation and evaluation of the intervention, and the influence of context. The data collection form also included key principles of theory driven evaluation proposed by Coryn, Noakes et al. (2011). These included how the programme theory was a) formulated, b) used to formulate and prioritise evaluation questions, c) plan and conduct evaluations, d) inform the measurement of constructs in the programme theory and e) provide a causal explanation. Where a paper described or showed a ToC, we assessed what elements of ToC they presented. The list of ToC elements was adapted from Vogel and included context, long-term change, process/sequence of change and assumptions (Vogel 2012). However, as there is no agreed upon assessment of quality for papers reporting ToC we did not asses the quality of the included papers. We did not contact authors for additional information.

Descriptive statistics were calculated using STATA 13 (Statcorp 2013). The papers were compared, evaluated and summarised narratively in relation to review questions. Due to the

heterogeneity of the study designs, interventions and outcomes included in this review, a meta-analysis was not conducted.

2.4 Results

2.4.1 Search results

In total, 566 abstracts were screened, resulting in 200 full text peer reviewed articles which were assessed for eligibility. An additional 65 records were identified from the grey literature search and screened for eligibility. A total of 62 papers were included (Bauer 1999, Vander Stoep, Williams et al. 1999, Barton, Powers et al. 2001, Birkby 2001, McQuiston, Choi-Hevel et al. 2001, von dem Knesebeck, Joksimovic et al. 2002, Weitzman, Silver et al. 2002, Bonner 2003, Veerman, De Kemp et al. 2003, Henderson 2004, Bauld, Judge et al. 2005, Carroll, David et al. 2005, De La Rosa, Perry et al. 2005, Goss-Power 2005, Gray and Seddon 2005, Mackenzie and Blamey 2005, Mason 2005, Secker, Bowers et al. 2005, Suarez-Balcazar 2005, Cole, Hogg-Johnson et al. 2006, Hernandez and Hodges 2006, Mackenzie 2006, Tucker, Liao et al. 2006, Mackenzie, Blamey et al. 2007, Carr, Lhussier et al. 2008, Riley, Byng et al. 2008, De La Rosa, Perry et al. 2009, Gregor 2009, Tran 2009, Weitzman, Mijanovich et al. 2009, Andreas, Ja et al. 2010, AusAID 2010, Bacchus, Bewley et al. 2010, Dixon-Woods, Tarrant et al. 2010, Levison-Johnson and Wenz-Gross 2010, Mackenzie, O'Donnell et al. 2010, Beeston, Robinson et al. 2011, Dixon-Woods, Bosk et al. 2011, Kreger, Sargent et al. 2011, Macfarlane, Greenhalgh et al. 2011, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Walker and Matarese 2011, Andersen, Nesman et al. 2012, Chandani, Noel et al. 2012, Knowlton and Phillips 2012, Levinson-Johnson 2012, Lund,

Tomlinson et al. 2012, Mackenzie, Reid et al. 2012, Maselli 2012, Morilus-Black, McCarthy et al. 2012, Reid and Botma 2012, Scanlon, Beich et al. 2012, Wenz-Gross and DuBrino 2012, Basson and Roets 2013, Bhattacharjee 2013, Brown, Hawkins et al. 2014, Illinois Caucus for Adolescent Health 2013, Kemp, Harris et al. 2013, Mookherji and LaFond 2013, Schierhout, Hains et al. 2013, Smith and Barnes 2013). Figure 2.1 is adapted from the PRISMA guidelines (Moher, Liberati et al. 2009) and summarises the search process and results.

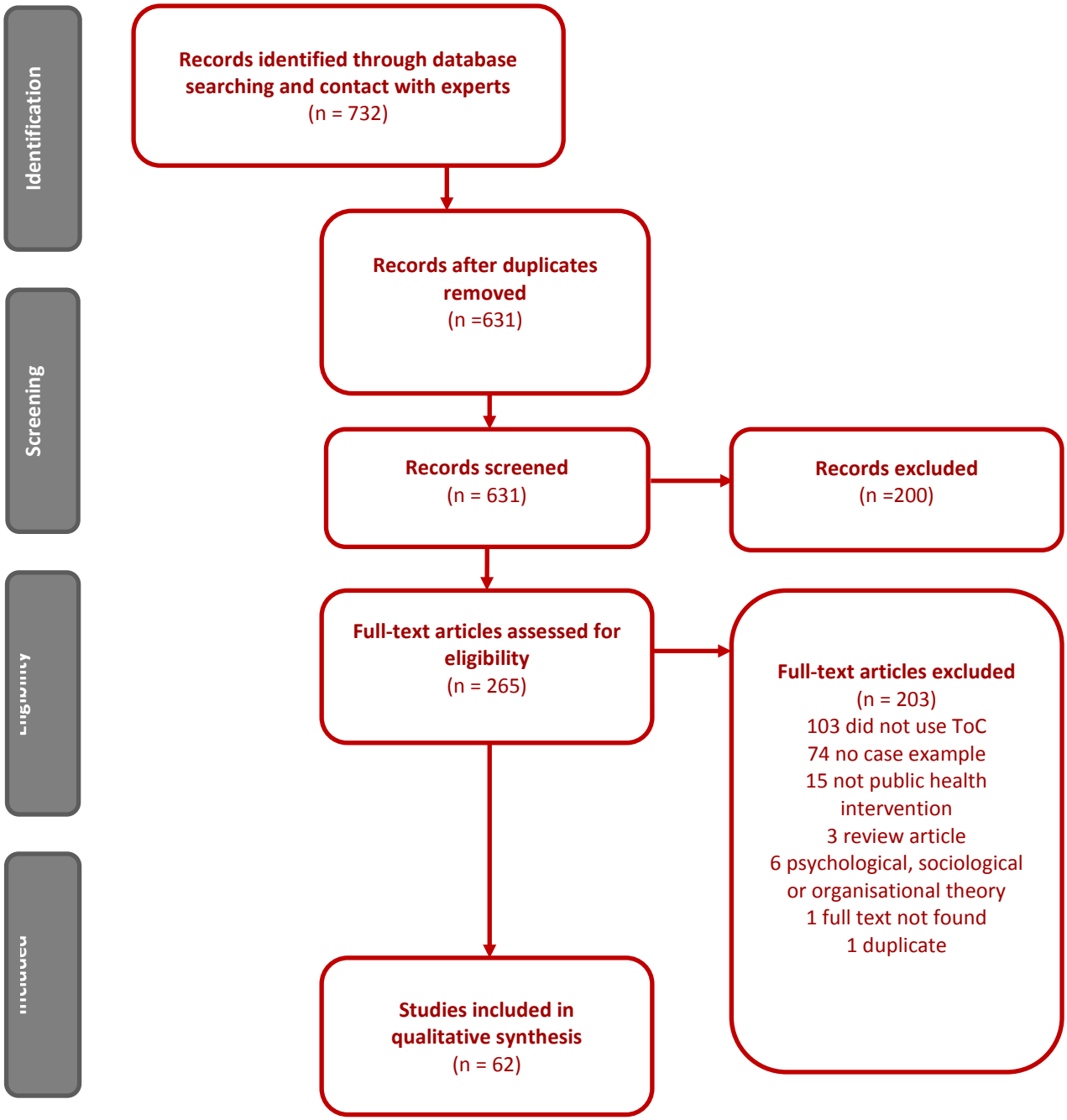

Figure 2-1 Results of Database, Abstract and Full Text Screening

2.4.2 Included studies

The publication dates of the papers range between 1999 and 2013, with a steady increase in papers over time (Figure 3.2). The majority were published in English in peer-reviewed journals but we also included PhD theses, presentations and NGO reports from the grey literature. Most of the research was conducted in the US or the UK. More details are provided in Table 3.1. Four pairs of papers reported on the same PHIs (Weitzman, Silver et al. 2002, De La Rosa, Perry et al. 2005, De La Rosa, Perry et al. 2009, Weitzman, Mijanovich et al. 2009, Levison-Johnson and Wenz-Gross 2010, Mackenzie, O'Donnell et al. 2010, Mackenzie, Reid et al. 2012, Wenz-Gross and DuBrino 2012). However, as the primary interest of this paper is how the use of ToC is described in reports and peer reviewed publications we have included them as separate papers.

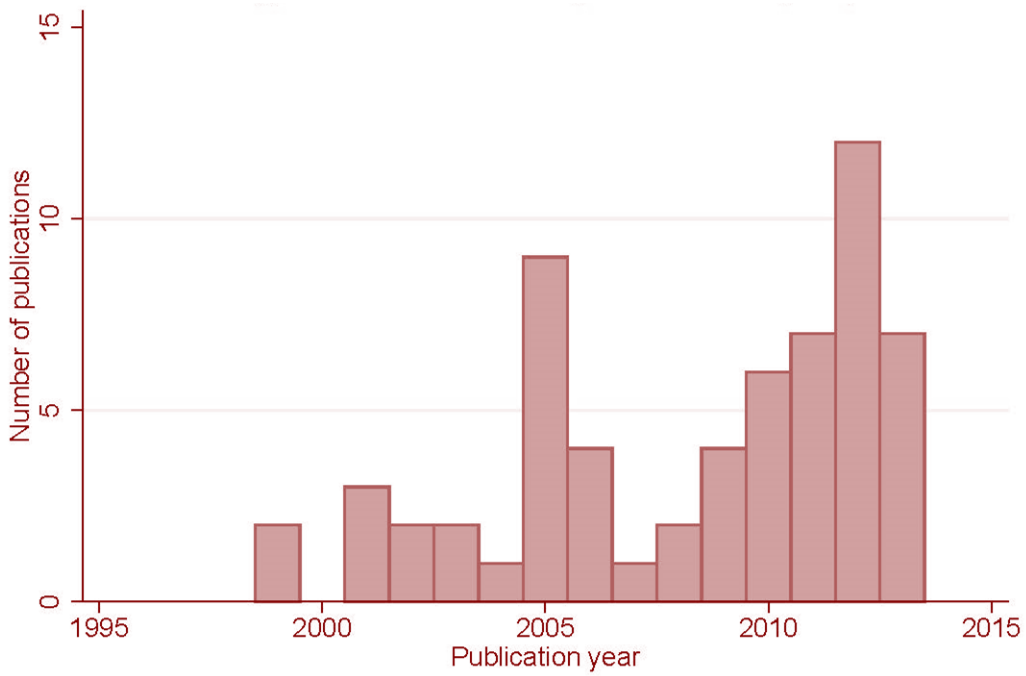

Figure 2-2 Histogram of number of publications per year

Table 2-1 Basic Descriptive Statistics of Included Papers

Variable	**n=62** **n (%)**
Language	
English	60 (96.7%)
Spanish	2 (3.2%)
Country	
US	28 (45.2%)
UK	20 (32.3%)
Other high income country	5 (8.1%)
Other low and middle income country	9 (14.5%)
Type of publication	
Grey literature	15 (24,2%)
Peer-reviewed journal article	47 (75.8%)
Public Health, Medicine and Nursing	*31 (50.0%)*
Psychology	*3 (4.8%)*
Social policy and social work	*6 (9.7%)*
Evaluation methods	*5 (8.1%)*
Other	*2 (3.2%)*
Use of TOC	
Describes development of ToC	49 (79.0%)
Describes the use of ToC in the development of the intervention	18 (29.0%)
Describes the use of ToC in the evaluation of the intervention	49 (79.0%)

A variety of PHIs reported using ToC in the design, development and evaluation of public health interventions (Table 3.2). These included systems of care for adolescents with behavioural and emotional difficulties (Hernandez and Hodges 2006, Weitzman, Mijanovich et al. 2009, Levison-Johnson and Wenz-Gross 2010, Macfarlane, Greenhalgh et al. 2011, Walker and Matarese 2011, Andersen, Nesman et al. 2012, Levinson-Johnson 2012, Maselli 2012, Morilus-Black, McCarthy et al. 2012, Wenz-Gross and DuBrino 2012, Illinois Caucus for

Adolescent Health 2013), substance use interventions (Henderson 2004, Andreas, Ja et al. 2010), domestic violence interventions (Bacchus, Bewley et al. 2010), comprehensive community initiatives (Bauer 1999, Birkby 2001, Weitzman, Silver et al. 2002, Mason 2005, Weitzman, Mijanovich et al. 2009), medication supply among community health workers (Chandani, Noel et al. 2012) and integrated district level mental healthcare plans in LMIC (Lund, Tomlinson et al. 2012).

Table 2-2 Characteristics of studies included in the review and reported aspects of the ToC process

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Andersen, Nesman et al. (2012)	US	Tampa Hillsborough integrated network for kids: respite care for families with seriously emotionally disturbed children	Reduction in caregiver burden	X			
Andreas, Ja et al. (2010)	US	Peer community approach to prevent substance use and recidivism in men and women in recovery who have been incarcerated	Prevention of substance abuse relapse	X			X
AusAID (2010)	Papua New Guinea	Strengthen sector wide response to HIV in Papua New Guinea	Stable HIV incidence rate; improved care for people living with HIV/AIDS	X			
Bacchus, Bewley et al. (2010)	UK	Guidelines, staff training, inclusion of routine enquiry for domestic violence with all patients, and referral of women disclosing violence to an on-site advocacy service.	Reduction in severity and frequency of abuse. Improved safety and access to resources	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Barton, Powers et al. (2001)	US	Promoting positive youth development for all young people	Reduction in drug and alcohol use, increase in immunisation rates				X
Basson and Roets (2013)	South Africa	A workplace wellness program for HIV affected nurses	Positive health and well-being of nurses	X	X		
Bauer (1999)	US	Oakland Community Based Public Health Initiative: a capacity and advocacy initiative for residents to impact on public health policy and training of public health professionals	Nil specific	X			X
Bauld, Judge et al. (2005)	UK	Health Action Zones: a multi area study in 26 local health areas aiming to identify and address the public health needs of the local area, to increase effectiveness and efficiency of services and develop partnerships	Improved health and reduced inequality.				X
Beeston, Robinson et al. (2011)	UK	A strategy for reducing alcohol related harm	Reduced alcohol related harms	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Bhattacharjee (2013)	India	A multipronged program targeting sex workers, their partners and the community to increase condom use and reduce violence towards sex workers	Increase in protected sex and decrease in STI/HIV transmission among sex workers	X	X		X
Birkby (2001)	US	Community partnerships for protecting children initiative on Child Maltreatment consisting of 5 strategic elements including casework training, family decision making, a hotline, community resource teams and substance abuse prevention and treatment	Reduction in serious injury	X			X
Bonner (2003)	UK	Program aimed at reducing drug taking and drug related harm	Reduction in drug taking and drug related harm among urban young people				X
Brown, Hawkins et al. (2014)	US	Communities that care: a manualised system for community coalitions to influence human and financial resources to address adolescent health and behaviour problems	Reduction in adolescent behaviour problems.				X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Carr, Lhussier et al. (2008)	UK	A walking group as part of the Positive Health Program funded by the Neighbourhood Renewal Fund	Enhanced physical fitness	X			X
Carroll, David et al. (2005)	UK	Workplace wellness program	Improved well-being of women clothing factory workers	X			X
Chandani, Noel et al. (2012)	International multicounty	Medication supply chains for community health workers in Rwanda, Ethiopia and Malawi	Sick children receive appropriate treatment for common childhood illness; CHWs have usable and quality medicines available for appropriate treatment of childhood illnesses	X	X		X
Cole, Hogg-Johnson et al. (2006)	Canada	Workplace economic program	Reduction in pain intensity and disability				X
De La Rosa, Perry et al. (2005)	US	A family based home visit intervention during pregnancy and after the birth of the first child	Improved Social support, caregiver behaviours, family interactions and	X	X		X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
			decreased personal problems affecting parenting.				
De La Rosa, Perry et al. (2009)	US	A family based home visit intervention during pregnancy and after the birth of the first child	Multiple including improved immunisation rates, connection with a medical home and maternal achievement of economic self-sufficiency.	X	X		X
Dixon-Woods, Bosk et al. (2011)	US	An intervention in intensive care units to reduce central venous catheter bloodstream infections	Decrease in intensive care unit mortality, hospital mortality, catheter related infections, ventilator associated pneumonia	X			X
Dixon-Woods, Tarrant et al. (2010)	UK	Safer Patient Initiative: introduction of patient safety into hospital management, culture and practice.	Increased patient safety in hospitals	X			
Goss-Power (2005)	US	VASE: a school for adolescents with emotional and	Nil specific				X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
		behavioural disturbances					
Gray and Seddon (2005)	UK	Two programs aimed at children in "trouble" at school, truancy and risk of social exclusion. 1. "Kick it" Football Project which included mentoring and drug education, 2. The Salford Anti-Rust gardening project using mentoring using horticulture	No specific health outcomes mentioned (mechanisms for change only)	X			X
Gregor (2009)	UK	Program which enables partnership between public and third sector organisations to deliver awareness-raising programs	Earlier presentation with TB, decrease in TC incidence Decrease in TB stigma, decreased barriers to access	X			X
Henderson (2004)	US	A substance abuse treatment program for homeless people	Sobriety, improved medical health			.	X
Hernandez and Hodges (2006)	US	Interagency service planning for youth who had been arrested and involved in juvenile probation	No specific health outcomes	X	X	X	

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Illinois Caucus for Adolescent Health (2013)	US	A network of youth and adults who advocate within school, family and healthcare systems to support sexual health, rights and identities of youth	Impacts school, family and healthcare systems in priority areas	X			
Kemp, Harris et al. (2013)	Australia	An ante- and post- natal home visiting program	Multiple including improved pre and postnatal maternal health and increased engagement with services	X			X
Knowlton and Phillips (2012)	US	A five arm strategic funding model to improve food security for children in the US	Improved US food security	X			X
Kreger, Sargent et al. (2011)	US	A network of coalitions and technical assistance programs who use an environmental justice approach to reduce risk factors for smoking	Healthier children and environments	X	X		X
Levinson-Johnson (2012)	US	A system of care for youth with behavioural and emotional problems and their families	Various health systems level changes	X	X		X
Levison-Johnson	US	A system of care for youth with behavioural and	Not described	X			

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
and Wenz-Gross (2010)		emotional problems and their families					
Lund, Tomlinson et al. (2012)	International multicounty	Programme for improving mental healthcare (PRIME): District specific mental health care plans which are integrated into routine health services	Not described	X	X		X
Macfarlane, Greenhalgh et al. (2011)	UK	Whole scale transformation of stroke, kidney and sexual health services including human resource management	Various including culture of health service and quality of care and service provision	X			X
Mackenzie (2006)	UK	Starting well: Intensive home visiting services for families of new babies in 2 areas in Scotland	Not described	X			X
Mackenzie and Blamey (2005)	UK	A multipronged heart disease prevention program	Reduce coronary heart disease	X			X
Mackenzie, Blamey et al. (2007)	UK	Choose life: a national strategy to reduce suicide in Scotland	20% reduction in suicide rates over a ten year period				X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Mackenzie, O'Donnell et al. (2010)	UK	Keep Well: The program identified those at risk of ill health and offered health checks and preventative services within primary and secondary care	Decreasing inequalities in cardiovascular morbidity and mortality in Scotland				X
Mackenzie, Reid et al. (2012)	UK	Keep Well: The program identified those at risk of ill health and offered health checks and preventative services within primary and secondary care	Decreasing inequalities in cardiovascular morbidity and mortality in Scotland				
Maselli (2012)	US	A comprehensive system of care which avoids re-traumatising children and youth with severe emotional challenges	None specific	X	X		X
Mason (2005)	UK	The Timely Tales (a community development and community arts project) was part of a larger Health Action Zone Project	None described	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
McQuiston, Choi-Hevel et al. (2001)	US	A culture specific program to empower lay heath advisers to promote sexual health and reduce sexually transmitted diseases	Promotion of sexual health and reduction of sexually transmitted diseases including HIV	X	X		
Mookherji and LaFond (2013)	International multicounty	Africa Routine Immunisation System Essentials (ARISE): using lessons from existing immunisations programs that have achieved solid advances in immunisation	Improved immunisation performance and equity	X			X
Morilus-Black, McCarthy et al. (2012)	US	An integrated system of care for children and families experiencing social and/or behavioural challenges	Improved care and referrals	X	X		X
Reid and Botma (2012)	South Africa	The program aims to expand public services to children with biomedical healthcare needs related to HIV	Nil specific	X			
Riley, Byng et al. (2008)	UK	The Lewisham Depression Programme: A multifaceted program which included marketing of the program, training and a depression recognition audit	Not mentioned	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Rivera, Martorell et al. (2011)	International multicounty	A master plan for the improvement of nutrition in Mesoamerica	Multiple including decreased mortality and increased maternal and child health	X	X		X
Rodriguez, Betanzos-Reyes et al. (2011)	International multicounty	A multifaceted strategic plan to eliminate malaria transmission in Mesoamerica	Eliminating local transmission of malaria in Mesoamerica	X	X		
Scanlon, Beich et al. (2012)	US	Quality Improvement alliance to improve quality in the healthcare system	Improvement in key community and population health outcomes	X	X		
(Schierhout, Hains et al. 2013)	Australia	A continuous quality improvement program in primary health care centres	Changes in deliver of guideline schedules services, focusing on diabetes and preventive care	X			X
Secker, Bowers et al. (2005)	UK	Preretirement health advice and services for people aged 50-65 years	Nil mentioned	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Smith and Barnes (2013)	UK	A whole systems approach to prevention of ill health	Improve quality of life, reduced social exclusion and reduced need for acute hospital care for older people	X			X
Suarez-Balcazar (2005)	US	A community intervention which assisted community members access health resources through the project's home web page and the internet.	Nil specific				X
Tran (2009)	UK	Provision of mental health advocacy delivered by a chines advocate with Cantonese and mandarin skills	Nil specific	X			X
Tucker, Liao et al. (2006)	US	Community strategies driven by 40 community coalitions to eliminate disparities in racial or ethnic groups for priority health areas	Reduction in health disparities	X	X		X
Vander Stoep, Williams et al. (1999)	US	A family centred system of care by community based teams for youth with mental health needs	Child's level of functioning	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Veerman, De Kemp et al. (2003)	Netherlands	Families First: a home-based intervention for children with behaviour problems	Nil specific				X
von dem Knesebeck, Joksimovic et al. (2002)	Germany	Systems interventions to improve local coordination of health and social care	Improved health care, health monitoring and health promotion				X
Walker and Matarese (2011)	US	A coaching, training and technical assistance model for wraparound	Not specified	X	X		
Weitzman, Silver et al. (2002)	US	Urban Health Initiative: a citywide multi-sector planning initiative	Improved health and safety outcomes for children and youth	X			X
Weitzman, Mijanovich et al. (2009)	US	Urban Health Initiative: a citywide multi-sector planning initiative	Improved health and safety outcomes for children and youth	X			X

Reference	Location(s)	Brief description of program	Health outcome	Development of TOC	TOC in intervention development	ToC in implementation	ToC in evaluation
Wenz-Gross and DuBrino (2012)	US	The program aims to decrease and prevent youths with serious emotional disturbance from becoming involved in the courts	Various including increased youth functioning and behavioural adjustment	X	X	X	X

2.4.3 Development of ToCs

Forty nine papers included some information on the ToC development process. Forty three percent of the papers developed their ToCs prospectively and 19.4% retrospectively. The ToCs were developed using workshops (McQuiston, Choi-Hevel et al. 2001, Secker, Bowers et al. 2005, Tucker, Liao et al. 2006, Gregor 2009, AusAID 2010, Bhattacharjee 2013, Mookherji and LaFond 2013) and working groups (Levison-Johnson and Wenz-Gross 2010, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Levinson-Johnson 2012, Maselli 2012, Wenz-Gross and DuBrino 2012), document reviews (Bauer 1999, Birkby 2001, Riley, Byng et al. 2008, Macfarlane, Greenhalgh et al. 2011, Schierhout, Hains et al. 2013), interviews and discussions (Bauer 1999, Birkby 2001, Mason 2005, Mackenzie 2006, Andreas, Ja et al. 2010, Macfarlane, Greenhalgh et al. 2011, Walker and Matarese 2011, Chandani, Noel et al. 2012, Morilus-Black, McCarthy et al. 2012, Reid and Botma 2012, Smith and Barnes 2013), surveys (Riley, Byng et al. 2008, Basson and Roets 2013), programme observation (Bauer 1999, Riley, Byng et al. 2008, Dixon-Woods, Tarrant et al. 2010, Macfarlane, Greenhalgh et al. 2011), literature reviews (Bauld, Judge et al. 2005, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Walker and Matarese 2011, Chandani, Noel et al. 2012) and existing conceptual frameworks (De La Rosa, Perry et al. 2005, De La Rosa, Perry et al. 2009, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Chandani, Noel et al. 2012, Kemp, Harris et al. 2013, Mookherji and LaFond 2013). The ToC development included consultations or interviews with the following stakeholders: programme staff (McQuiston, Choi-Hevel et al. 2001, Secker, Bowers et al.

2005, Mackenzie 2006, Carr, Lhussier et al. 2008, Riley, Byng et al. 2008, Andreas, Ja et al. 2010, Dixon-Woods, Tarrant et al. 2010, Levison-Johnson and Wenz-Gross 2010, Kreger, Sargent et al. 2011, Chandani, Noel et al. 2012, Morilus-Black, McCarthy et al. 2012, Reid and Botma 2012, Wenz-Gross and DuBrino 2012, Smith and Barnes 2013), management (Vander Stoep, Williams et al. 1999, Mackenzie 2006, Maselli 2012, Reid and Botma 2012, Scanlon, Beich et al. 2012, Wenz-Gross and DuBrino 2012), families (Vander Stoep, Williams et al. 1999, Levison-Johnson and Wenz-Gross 2010, Andersen, Nesman et al. 2012, Morilus-Black, McCarthy et al. 2012, Wenz-Gross and DuBrino 2012), service users (Carroll, David et al. 2005, Maselli 2012, Morilus-Black, McCarthy et al. 2012, Illinois Caucus for Adolescent Health 2013), experts (Chandani, Noel et al. 2012, Mookherji and LaFond 2013) and evaluators (Vander Stoep, Williams et al. 1999, Mackenzie and Blamey 2005, Carr, Lhussier et al. 2008, Tran 2009, Weitzman, Mijanovich et al. 2009, Kreger, Sargent et al. 2011, Knowlton and Phillips 2012, Maselli 2012, Scanlon, Beich et al. 2012). Many used multiple methods, for example, Mookheriji and Lafond used immunisation programme theory and discussion with programme stakeholders, including immunisation experts, to develop a ToC of routine immunisation performance (Mookherji and LaFond 2013). After the evaluation was completed using a case study approach, the ToC was refined at a stakeholder workshop with 21 participants to take into account the results of the evaluation.

The resultant ToCs were described using narrative summaries (n=15, 34.1%), diagrams (n=22, 50%) or both (n=6, 13.6%). Table 2.3 outlines the components of the ToCs that were described. Almost all of the ToCs outlined the long term outcome required and the majority described the process or sequence of change. However, assumptions and indicators were displayed or described infrequently.

Table 2-3 Components of ToC in the papers where a ToC was displayed or described. Essential and additional components adapted from Vogel (2012)

ToC components	n=44 n (%)
Essential	
Long-term change	40 (90.9%)
Process/sequence of change	33 (75%)
Context	24 (54.5%)
Assumptions	7 (15.9%)
Additional	
Strategic choices and intervention options	23 (52.3%)
Beneficiaries	20 (45.5%)
Actors in the context	13 (29.5%)
Timeline	4 (9.1%)
Indicators	4 (9.1%)
Sphere of influence	3 (6.8%)

2.4.4 Using ToCs to design Public Health Interventions

Eighteen papers (29%) described the use of ToC in the development of a public health intervention. The majority of these reported that they used the ToC as a framework for the intervention (De La Rosa, Perry et al. 2005, Hernandez and Hodges 2006, De La Rosa, Perry et al. 2009, Scanlon, Beich et al. 2012, Basson and Roets 2013) or as a basis for a strategic plan (Tucker, Liao et al. 2006, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Maselli 2012, Wenz-Gross and DuBrino 2012). Some examples of how ToCs were used to design public health interventions follow. Basson et al. used formative research to

develop a ToC for a workplace wellness intervention for HIV affected nurses and presented this programme theory as a framework for future research. Lund et al. used stakeholder workshops to develop their ToC and then used this to refine the substance and delivery of integrated district mental healthcare plans in five LMIC (Lund, Tomlinson et al. 2012). A few presentations and papers reporting the development of systems of care for children with behavioural difficulties used the ToC as an outline of their PHI and as a basis for their strategic plan (Hernandez and Hodges 2006, Maselli 2012, Morilus-Black, McCarthy et al. 2012). Chandani et al. (Chandani, Noel et al. 2012) used the ToC to frame the results of their formative work and used the ToC to identify interventions to address the bottlenecks to the availability of essential medicines among community health workers in Ethiopia, Malawi and Rwanda.

2.4.5 Using ToCs to evaluate Public Health Interventions

Forty-nine papers (79%) describe the use of ToC in the evaluation of the intervention. This includes the development of indicators, the overall evaluation design and data analysis.

The development of indicators used in the ToC was described in 28 papers. The indicators were often developed from the short, medium or long term outcomes described in the ToC (Birkby 2001, Mackenzie and Blamey 2005, Suarez-Balcazar 2005, Carr, Lhussier et al. 2008, Weitzman, Mijanovich et al. 2009, Andreas, Ja et al. 2010, Morilus-Black, McCarthy et al. 2012, Clarke, Godfrey et al. 2013). Thirty-two (51.6%) measured process constructs, 28 (45.2%) measured outcome constructs and 9 (14.5%) measured contextual constructs

described in the ToC. Only two papers (Hernandez and Hodges 2006, Wenz-Gross and DuBrino 2012) explicitly described the use of ToC to identify indicators for ongoing monitoring of the implementation of the intervention.

The majority of papers (62.9%) reported formulating their evaluation questions around the ToC. However, the papers varied in the amount of detail they provided on this process. A common description was that the ToC was used to provide a framework for the evaluation (von dem Knesebeck, Joksimovic et al. 2002, Veerman, De Kemp et al. 2003, Bauld, Judge et al. 2005, Secker, Bowers et al. 2005, Suarez-Balcazar 2005, Gregor 2009, Weitzman, Mijanovich et al. 2009, Andreas, Ja et al. 2010, Beeston, Robinson et al. 2011, Wenz-Gross and DuBrino 2012, Mookherji and LaFond 2013). Others reported that they used the evaluation to develop (Carroll, David et al. 2005), refine (Chandani, Noel et al. 2012) or validate the ToC (Mookherji and LaFond 2013). Two papers reported that their evaluation was guided by testing the assumptions in the ToC (Bacchus, Bewley et al. 2010, Bhattacharjee 2013).

The data collection and analysis methods used varied greatly across papers. Data collected for the evaluation included routinely collected data (Beeston, Robinson et al. 2011, Dixon-Woods, Bosk et al. 2011), custom designed surveys (Bauer 1999, von dem Knesebeck, Joksimovic et al. 2002, Weitzman, Silver et al. 2002, Bauld, Judge et al. 2005, Secker, Bowers et al. 2005, Tucker, Liao et al. 2006) and qualitative data. Qualitative data collection methods included interviews (Birkby 2001, von dem Knesebeck, Joksimovic et al. 2002, Weitzman, Silver et al. 2002, Gray and Seddon 2005, Tran 2009, Andreas, Ja et al. 2010, Schierhout, Hains et al. 2013, Smith and Barnes 2013), programme observation (Birkby

2001, Weitzman, Silver et al. 2002, Andreas, Ja et al. 2010), programme documentation (Birkby 2001, von dem Knesebeck, Joksimovic et al. 2002, Weitzman, Silver et al. 2002, Tran 2009, Schierhout, Hains et al. 2013) and visual evidence (Bauld, Judge et al. 2005) . The quantitative data analysis methods were strongly linked to the types of data collected and included descriptive statistics (Beeston, Robinson et al. 2011), inferential statistics (Veerman, De Kemp et al. 2003, De La Rosa, Perry et al. 2005, Suarez-Balcazar 2005, De La Rosa, Perry et al. 2009, Andreas, Ja et al. 2010, Chandani, Noel et al. 2012), multilevel modelling (Bauer 1999) and path analysis (Cole, Hogg-Johnson et al. 2006). Other methods included case study approaches (Bauer 1999, Bonner 2003, Beeston, Robinson et al. 2011, Mookherji and LaFond 2013) and iterative thematic analysis (Schierhout, Hains et al. 2013) and whereas others did not explicitly state their specific data analysis approach (Vander Stoep, Williams et al. 1999, Knowlton and Phillips 2012).

Few papers explicitly explored the influence of context of the intervention in relation to ToC. Although some ToCs mentioned context, particularly those with a realist evaluation focus, there was little description of how context affected the interpretation of the evaluation. There were some exceptions (Secker, Bowers et al. 2005, Macfarlane, Greenhalgh et al. 2011, Chandani, Noel et al. 2012, Mookherji and LaFond 2013). Mookherji and LaFond used a case study approach to explore what worked within and between immunisation programme contexts to identify common factors influencing immunisation performance in Ghana, Ethiopia and Cameroon (Mookherji and LaFond 2013). For example, political and social commitment to routine immunisation was seen as a key factor in influencing immunisation performance although it was described slightly differently for each context. Similarly, Chandani et al. developed a cross- country ToC of community health worker

supplied medication in Ethiopia, Malawi and Rwanda. They compared whether each of the pre-conditions and the outcome was achieved in each setting (Chandani, Noel et al. 2012). These differences were then explained based on the contextual factors in each setting such types of medication provided by the health workers, standard operating procedures and data availability and means of transport and travel times. Secker, Bowers et al. (2005) explored the influence of socioeconomic and demographic characteristics as well as infrastructure and organisational processes and systems between 8 pilot sites in the evaluation of a pre-retirement health initiative.

2.4.6 Using ToC to provide causal explanations

Few papers reported on the identification of breakdowns and side effects, effectiveness or efficacy and causal explanations as described by Coryn, Noakes et al. (2011). Only four (6.5%) identified breakdowns of programme theory, three (4.8%) identified unexpected consequences of the intervention, ten (16.1%) made cause-and-effect associations between theoretical constructs explicit, two (3.2%) described differences in direction and/or strength of relationship between programme and outcomes and two (3.2%) described the extent to which one construct accounted for/mediated the relationship between other constructs.

2.5 Discussion

In this systematic review we provide an overview of how ToCs have been developed and used to develop and evaluate public health interventions. As expected, there is variation in

how ToCs are developed and used in evaluation though the papers report very little detail about the ToC process.

We have shown that the ToC approach has been in use since at least 2005 with 62 reports in peer reviewed articles and grey literature. This was significantly more than expected, given that Coryn et al. Coryn, Noakes et al. (2011) found only three papers describing theory driven evaluation of health interventions using ToC. Overall, many papers provided little detail in relation to the process of ToC development and how the ToC was used to design the intervention or conduct the evaluation. For example, Bonner (2003) describes the ToC approach in detail but provides only a short example the Health Action Zones experience of using ToC to evaluate an intervention to reduce drug taking. Brown, Hawkins et al. (2014) report using a ToC approach to evaluate a health promotion intervention for adolescents. The only description of ToC was found in the abstract and then mentioned briefly in the discussion. There was no clarity on how the ToC was developed or any explicit mention of how it was used to inform the analysis. The lack of detail may explain the discrepancy with the review by Coryn et al. which included only papers that reported use of ToC for evaluation and excluded those that did not provide enough detail (Coryn, Noakes et al. 2011).

In contrast, other papers provided extensive detail on the ToC development process. For example, Hernandez and Hodges (2006) describe the 12 step process used to develop a ToC for interagency delivery of mental health services for children with serious emotional disturbances and their families. They describe each step in detail including the purpose of the stage of the process, the types of stakeholders participating in the step, the substance of

the discussions and the decisions reached. The ToC was then displayed as a logic model for readers to gain a better understanding of the output of the process. Similarly, Mookherji and LaFond (2013) described in detail their approach to developing their initial ToC and how the ToC was used to determine case selection for a comparative case study. They then described how they used the results of the comparative case study and the ToC workshops to refine their ToC.

A range of methods were used to develop ToCs. The methods ranged from participatory methods which encourage stakeholder participation and ownership of the ToC such as workshops and working groups, to more evaluator focused approaches such as programme observation and review of programme documentation. Although the reason for the choice of methods was rarely made explicit by the authors, these methods were presumably chosen based on the purpose, depth and level of stakeholder buy-in the ToC required. For example, the examples of the development of systems of care for children and adolescents with mental and behavioural disorders, viewed stakeholder participation as very important and therefore held a series of workshops with multiple stakeholders from different government departments, service providers, families and service users (Hernandez and Hodges 2006, Maselli 2012, Illinois Caucus for Adolescent Health 2013). In some cases, although stakeholders were interviewed or participated in surveys, they did not contribute explicitly to the development of the ToC (Bauer 1999, Mackenzie 2006). Sullivan and Stewart (Sullivan and Stewart 2006) argue that although participation of all stakeholders in the development of ToC is the ideal presented by Weiss and colleagues (Weiss 1995), this is not always practical or feasible. They argue that different types of ToC development and

resulting ownership may have advantages and it is important to be explicit about the development process.

The lack of detail in most of the examples in the review makes it difficult to assess the thoroughness of ToC development. In many cases, ToC seems to have been developed superficially and then used in a cursory way during evaluation. Similarly, where ToCs were shown in diagrammatic form or described in narrative form, they often contained very little detail. Most ToCs showed or described the long term outcomes, sequence of change, beneficiaries and context. However, very few showed assumptions although Vogel identifies these as a core part of ToC (Vogel 2012). Where ToC was used to develop the interventions it was often not clear how this was done apart from providing an overarching framework or strategic plan for the intervention.

A surprising finding of the review the paucity if papers describe the use of ToC for use during the implementation of the intervention (n=2). Given the popularity of ToC as a monitoring and evaluation tool in the international development sector (Vogel 2012), we had expected that more papers would use ToC during the implementation phase to assess progress towards the outcomes as well as modify implementation where necessary.

ToC theorists such as Connell and Kubisch (1998) emphasise that the ToC approach to evaluation is method neutral and, as such, does not prescribe a specific type of study design or evaluation method. This was reflected in the papers included in this review which used variety of qualitative and quantitative data collection and analysis methods. This flexibility in methods can be an advantage if researchers can design evaluations which seek to

understand and evaluate both the outcomes and causal mechanisms which are made explicit in the ToC. However, flexibility in methods may also result in evaluations being poorly formulated in terms of the appropriateness of the methods, the rigor of data analysis, or the results not interpreted in light of the ToC. In this review, evaluations were often described in detail but it was not clear how they linked to the ToC or how the ToC was used to interpret the results. However, some authors clearly develop or refine their ToCs as the results of the evaluation emerge. For example, Carroll, David et al. (2005) sought to describe a theory of change for health promotion activities for hard to reach groups which was developed through the evaluation.

Most papers failed to explicitly discuss the results of the ToC in relation to unexpected outcomes, direction of causation and mediation of effects. This is similar to the conclusions drawn be Coryn et al. who report that programme theory was not used in any meaningful way to develop evaluation questions or plan, conduct and interpret the analysis (Coryn, Noakes et al. 2011).

It is interesting to note that no studies used ToC alongside randomised controlled trials (RCTs) as a method to unpack the programme theory underpinning the intervention. As we have noted previously ToC holds much potential for this as RCTs alone are no longer considered adequate for the evaluation of complex health interventions (De Silva, Breuer et al. 2014).

Detailed reporting of the ToC process is particularly important as definitions of ToC differ considerably (Vogel 2012). Many papers did not define ToC. However, there were clear

overlaps with other theory driven evaluation approaches, in particular, realist approaches (Bonner 2003, Bauld, Judge et al. 2005, Carr, Lhussier et al. 2008, Macfarlane, Greenhalgh et al. 2011) and logic models (Hernandez and Hodges 2006, Tucker, Liao et al. 2006, Levison-Johnson and Wenz-Gross 2010, Kreger, Sargent et al. 2011, Rivera, Martorell et al. 2011, Rodriguez, Betanzos-Reyes et al. 2011, Andersen, Nesman et al. 2012, Maselli 2012, Morilus-Black, McCarthy et al. 2012, Reid and Botma 2012, Wenz-Gross and DuBrino 2012, Basson and Roets 2013). Realist approaches have a different theoretical basis to ToC and differ in several ways including the how they articulate and generate theory, the degree to which stakeholders are involved and the types of knowledge they seek to generate (Blamey and Mackenzie 2007). Marchal et al. (Marchal, van Belle et al. 2012), in a systematic review on realist evaluation in health systems research, also noted that ToC and realist evaluation were often used together or interchangeably. Logic models are conceptually similar to ToC, but are usually presented in a linear form with boxes for inputs, activities, outputs and outcomes with little explanation of the causal pathways linking them (De Silva, Breuer et al. 2014). Reducing a ToC to a logic model may conceal some of the explanatory power of the causal pathways.

Two limitations to this review were the lack of double data extraction and the inability to effectively measure the quality of the included papers. We did extract data on a checklist of ToC components proposed by Vogel (Vogel 2012) and principles of theory driven evaluation by Coryn et al. (Coryn, Noakes et al. 2011) but it was difficult to make an assessment of quality. This is primarily because there is no agreed upon quality criteria for ToC. This is compounded by the flexibility of the ToC approach, both in the development of ToCs and how they can be used for evaluation. In addition the various definitions of the ToC

approach, the absence of detail in reporting, the inclusion of papers which did not necessarily include an evaluation and our decision to not contact authors for additional information. Because evaluations using ToC vary in study design and method, existing methodological checklist are of little use for comparative purposes.

We suggest that authors planning to report on ToC to guide the development or evaluation of public health interventions provide more detail on the ToC process to readers. In particular, it is important to make the ToC used explicit and this is usually easier in diagrammatic form. Complex ToCs can be simplified in a summary model with detailed ToCs provided as web appendices. This allows the reader to understand the authors' expected pathways of change and judge their validity. In addition, it is imperative that authors describe in detail how the ToC was developed and used. This is particularly important as there is no single way to develop or use a ToC. Making the process explicit helps readers judge the credibility of the ToC and strengthen the literature in this field.

We have therefore developed a checklist based on this review and the work of Coryn, Noakes et al. (2011) and Vogel (2012) which can assist with the clearer reporting of the ToC approach. The checklist gives guidance as to which aspects of the ToC should be made explicit (Table 2.4). It covers five domains, namely the 1) definition of ToC; 2) description of the ToC development process; 3) ToC diagram; 4) process of intervention development; and 5) use of ToC in evaluation. The checklist would benefit from expert review and piloting in the real world. However, it provides a starting point for authors reporting a ToC approach. As ToC is method neutral, this checklist could also be used together with other existing checklists such as the CONSORT statement for RCTs (Schulz, Altman et al. 2010) or the

STROBE guidelines for observational research (Vandenbroucke, Von Elm et al. 2007) or the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI2) for complex intervention development and evaluation (Möhler, Köpke et al. 2015).

Table 2-4 Checklist for reporting ToC in Public Health Interventions

1.	**Is the ToC approach defined?**
a.	Is a definition of ToC given by the authors?
b.	Do the authors explain their reasons for using a ToC approach?
2.	**Is the ToC development process described?**
a.	Are the methods used to develop the ToC, such as stakeholder meetings and interviews, document reviews, programme observation, existing conceptual frameworks or published research, described?
b.	Where stakeholders are involved, is it clear how many stakeholders participated, what their role is in relation to the intervention, how they were consulted (e.g. number of interviews, focus groups, ToC workshops) and the extent to which the consultations were participatory?
c.	Is the method used to compile the data into a ToC described? (including how disagreements between stakeholders were resolved)
d.	Is the extent to which stakeholders were able to validate the resultant ToC and were owners of the final product described?
3.	**Is the resultant ToC (or a summary thereof) depicted in a diagrammatic form and does it include?**
a.	The long term outcome or impact of the intervention
b.	The anticipated short and medium term outcomes and the process of change
c.	The intervention components which happen at different stages of the pathway
d.	The context of the intervention
e.	Assumptions about how change would occur
f.	Additional ToC elements such as indicators, supporting research evidence, beneficiaries, actors in the context, sphere of influence and timelines where relevant.
4.	**Is the process of intervention development from the ToC described?**
a.	Are the methods of how interventions were refined from the ToC to something which can be

	implemented? (For example, further stakeholder workshops, interviews, systematic literature reviews)
5.	**Is the way in which the ToC was used to develop and implement the evaluation described?**
	a. Are evaluation research questions generated from the ToC?
	b. Is the role of ToC in the design, plan or conduct of the evaluation clear?
	c. Does the paper describe the extent to which the key elements described in the ToC were measured in the evaluation (i.e. impact, short and medium term outcomes and the process of change, context, assumptions and the intervention)?
	d. Does the paper describe whether and how process indicators were used to improve the quality of the intervention?
	e. Is the role of the ToC in the analysis of the results of the evaluation clear?
	f. Is the role of ToC in the interpretation of the results of the evaluation described? (including the breakdown of programme theory, unanticipated outcomes and causation including the strength and direction of causal relationships)

2.6 Conclusion

The ToC approach is widespread in the public health literature. Clear reporting of the ToC process and outputs are important to improve allow the readers a thorough understanding of the work and allows them to judge the validity of the approach. We recommend that our proposed checklist is used and refined by authors reporting the ToC approach.

2.1 Declarations

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2.1.2 Competing interests

The authors declare no conflicts of interest.

2.1.3 Authors' contributions

EB designed the study under the guidance of MDS and CL. The protocol for the review was developed by EB with input from LL, MDS and CL. EB and LL double screened all abstracts and full text articles. EB conducted the data extraction and drafted the manuscript. All authors gave feedback on the draft manuscript and read and approved the final manuscript

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Chapter 3. Using workshops to develop theories of change in five low and middle income countries: lessons from the programme for improving mental health care (PRIME)

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3.1 Abstract

3.1.1 Background

The Theory of Change (ToC) approach has been used to develop and evaluate complex health initiatives in a participatory way in high-income countries. Little is known about its use to develop mental health care plans in low and middle income countries where mental health services remain inadequate.

3.1.2 Aims

ToC workshops were held as part of formative phase of the Programme for Improving Mental Health Care (PRIME) in order 1) to develop a structured logical and evidence-based ToC map as a basis for a mental health care plan in each district; (2) to contextualise the

plans; and (3) to obtain stakeholder buy-in in Ethiopia, India, Nepal, South Africa and Uganda. This study describes the structure and facilitator's experiences of ToC workshops and critically reflects on how the purposes of the workshop were achieved within a hierarchical health system.

3.1.3 Methods

The facilitators of the ToC workshops were interviewed and the interviews were recorded, transcribed and analysed together with process documentation from the workshops using a framework analysis approach.

3.1.4 Results

Thirteen workshops were held in the five PRIME countries at different levels of the health system. The ToC workshops achieved their stated goals with the contributions of different stakeholders. District health planners, mental health specialists, and researchers contributed the most to the development of the ToC while service providers provided detailed contextual information. Buy-in was achieved from all stakeholders but valued more from those in control of resources.

3.1.5 Conclusions

Facilitators reported that ToC workshops are a useful approach for developing ToCs as a basis for mental health care plans because they facilitate logical, evidence based and contextualised plans, while promoting stakeholder buy in. Because of the existing

hierarchies within some health systems, strategies such as limiting the types of participants and stratifying the workshops can be used to ensure productive workshops.

3.2 Background

Mental health services remain inadequate in low and middle-income countries (LMIC). They are marked by low financial investment, insufficient human resources and lack of political priority and planning for mental health care (Saraceno, Van Ommeren et al. 2007, WHO 2011). In order to expand and improve access, it is imperative that mental health is integrated into primary health care and other health platforms as well as into the services provided by other sectors including education, social services, justice and labour (Collins, Insel et al. 2013). Although evidence exists for individual evidence based interventions, less is known about how they can be integrated into existing health services (Dua, Barbui et al. 2011). Engaging key stakeholders in participatory planning for mental health services is critical to develop such services and resources, get local and national stakeholder buy-in, and develop plans that are contextually appropriate (Israel, Schulz et al. 1998, Gilson 2012).

Theory of Change (ToC) is a participatory theory driven approach to programme design and evaluation whose underlying principle is to improve our understanding of how and why a programme works (Weiss 1995). This is achieved through the development of a ToC, or programme theory, which describes the causal pathways through which a programme is hypothesised to have an effect. The ToC is often developed in consultation with key stakeholders in ToC workshops or interviews, document review or programme observation (Mason and Barnes 2007). Social science, management, sociological or other formal theories are inserted into the framework to explain why and how the causal pathways operate

(Mason and Barnes 2007, Coryn, Noakes et al. 2011). The ToC is often displayed visually as a ToC map (Andersen 2004).

The ToC approach was developed from theory driven evaluation approaches which include the logical frameworks and logic models (Funnell and Rogers 2011) and has been influenced by informed social action approaches (Vogel 2012). Although often used exclusively as an evaluation tool, Connell and Kubisch, in one of the seminal articles on ToC, proposed that it be used both in for programme development and evaluation (Connell and Kubisch 1998).

Interest in the ToC approach has grown recently in the development and NGO sector. ToC has been used by agencies such as DFID, Oxfam, and Comic Relief (James 2011) for both program design and evaluation. Despite the abundance of guidelines on how to develop a ToC (Andersen 2004, James 2013, Taplin, Clark H et al. 2013) and its widespread use there are few published case reports of their application in the academic literature and the majority of these describe the use in evaluation of programmes and not their design. There are only a few examples in the academic literature describing the role of ToC in the planning of complex health interventions (Levinson-Johnson 2012, Reid and Botma 2012). These include the use of ToC in the development and evaluation of mental health systems of care for children and adolescents in the US (Hernandez and Hodges 2006, Walker and Matarese 2011). Results from these experiences show that ToC can be used effectively as a planning tool for implementation as well as provide a framework for evaluation (Hernandez and Hodges 2006). In addition, using ToC provides a mechanism for consensus building amongst stakeholders and a shared service delivery strategy.

There is very little detail published on how ToCs have been developed. Methods of ToC development reported in the literature include review of programme documentation (Hernandez and Hodges 2006), interviews and focus group discussions with key stakeholders (Cole 2003, Mason and Barnes 2007, Reid and Botma 2012), using existing theory or research (Basson and Roets 2013, Kemp, Harris et al. 2013) and ToC workshops (Mason 2005) but few describe their methods in enough detail to replicate the ToC development.

Proponents of ToC advocate for the use of ToC workshops to develop ToCs as they allow participation of various stakeholders who can share knowledge, debate specific aspects of the ToC, articulate assumptions, and assess the feasibility of the intended interventions in the specific context (Connell and Kubisch 1998, Mason 2005). For example, Mason and Barnes (2007) used ToC workshops with key stakeholders to develop a ToC for the evaluation of the New Children's Fund, a multi-agency collaboration to deliver preventive services for children. During the workshops, they explored the needs of the target group, the short, medium and long terms outcomes the programme was working to address, the activities through which the outcomes could be achieved, the rationale of the activities, and the local and national policy context. However, few additional examples of ToC workshops have been published in the academic literature (Hunter 2006) and, to our knowledge, none use ToC workshops to develop an intervention within a health system in LMIC.

The majority of the guidance on how to conduct ToC workshops has been developed by funding and development organisations which outline how ToC workshops can be conducted. A common approach starts with stakeholders reaching agreement on the

intended *impact*, then working backward to determine the intermediate and short term *outcomes* necessary and sufficient to achieve the intended impact (Andersen 2004, Taplin and Rasic 2012). These outcomes are operationalized by identifying *indicators* for each outcome which will determine whether the outcome has been achieved. In addition, the evidence base or *rationale* of how one outcome leads to the next is articulated and whether an *intervention* is required to achieve this. Stakeholders are encouraged to articulate the *assumptions* underlying the theory as well as to decide a *ceiling of accountability* where the programme is no longer directly responsible for the outcomes achieved. The ultimate ToC should be plausible, do-able and testable (Connell and Kubisch 1998) and can be represented graphically in a ToC map (Figure 3.1).

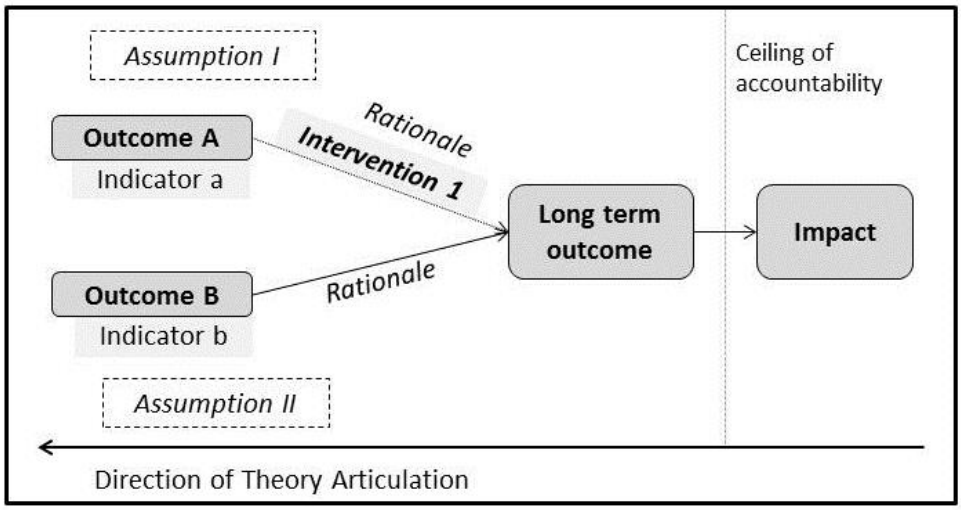

Figure 3-1 Elements of a Theory of Changes (adapted from Andersen (2004)).

3.2.1 The programme for improving mental health care (PRIME)

The Programme for Improving Mental Health Care (PRIME) is a multi-country research programme which aims to provide evidence for how to integrate mental health into primary care by developing, implementing and evaluating district level mental health care plans (MHCPs) for priority disorders (Lund, Tomlinson et al. 2012). It is working in pilot districts or sub-districts in five LMIC, namely in Sodo, Ethiopia; Sehore, India; Chitwan, Nepal; Dr Kenneth Kaunda, South Africa; and Kamuli, Uganda (Table 3.1). Mental health service resources vary considerably across the district sites. Still, all countries face health systems and contextual challenges (Hanlon, Luitel et al. 2014). Within each district, specific packages of mental health care made up of several interacting components have been developed for implementation within three levels of the health system: healthcare organisation, health facility and community. The PRIME MHCPs target three priority disorders: depression, alcohol use disorders and psychosis, with the addition of epilepsy in Ethiopia, Nepal and Uganda. One of the key principles of PRIME is a partnership between researchers and the Ministries of Health in each of the PRIME countries. As part of this partnership, the human resources for the implementation of PRIME are largely provided by the Ministries of Health while the researchers provide training, technical support and evaluation (Lund, Tomlinson et al. 2012). As such, the PRIME MHCPs meet the criteria for complex interventions as outlined by Craig, Dieppe et al. (2008) including multiple groups of stakeholders and organisational levels targeted by the intervention. The intervention achieves multiple outcomes through several causal strands.

Table 3-1 Baseline information for PRIME District sites prior to implementation. Adapted from Lund, Tomlinson et al. (2012)

Country	World bank region[1]	World bank income classification[1]	Gross national income per capita (USD) [1]	PRIME District/sub-district	Population[2]	Socio-economic characteristics[2]	Number of Health Facilities[2]	Number of MH specialists[2]
Ethiopia	Sub-Saharan Africa	Low Income	400	**Sodo**	165,000	Literacy rate = 22%; 90% rural	0 hospitals, 1 district health bureau, 7 community health centers, 52 health posts	None
India	South Asia	Lower middle income	1410	**Sehore (Madhya Pradesh state)**	1,311,008	Literacy rate: 71% 81% rural	2 hospitals, 8 community health centers, 15 primary health clinics	1 part-time psychiatrist, 1 psychologist
Nepal	South Asia	Low income	540	**Chitwan**	575,058	Literacy rate = 70% 73% rural	152 sub –health centers	2 Psychiatrists
South Africa	Sub-Saharan Africa	Upper Middle Income	6960	**Kenneth Kaunda (North West Province)**	632,790	Literacy rate: 88% 14% rural	2 hospitals, 4 primary health centers, 5 health posts	1 Psychiatrist, 1 Psychologist
Uganda	Sub-Saharan Africa	Low Income	500	**Kamuli**	740,700	Literacy rate: 62% 3% rural	41 sub-health posts	1 Psychiatric Clinical Officer

[1] World Bank (2012) [2] Lund, Tomlinson et al. (2012)

The PRIME MHCPs have been developed for each district through formative work including reviews of the literature, a situational analysis of mental health care in the district (Hanlon, Luitel et al. 2014), semi structured interviews and focus group discussions with stakeholders (Jordans, Luitel et al. 2013). As part of the development of the PRIME MHCPs we used a ToC approach which involved the development of a PRIME cross-country and district specific ToCs.

This paper describes how the district specific workshops can be used in the planning stages of a complex mental health intervention. Specifically, we describe the overall structure and stakeholder composition of the PRIME ToC workshops and reflect on the facilitators' experiences of how stakeholders contributed to the three purposes of the ToC workshops. The purposes were to 1) develop a logical evidenced based ToC map, 2) inform the development of a contextualised mental health care plan; and, 3) obtain the buy-in of key stakeholders. We critically reflect on how these purposes were achieved within a hierarchical health system, how different stakeholders contributed to these purposes and potential approaches to and limitations of mitigating the effects of this hierarchy.

3.3 Methods

3.3.1 The ToC process in PRIME

The ToC process began by developing an initial PRIME cross-country ToC in a workshop attended by 15 key PRIME partners, including two representatives from each PRIME country team, in Goa, India in October 2011. The workshop aimed to both introduce the PRIME

partners to the ToC approach and to develop a PRIME cross country ToC as a framework for the district level MHCPs.

The ToC developed during this workshop identified the intended impact of the PRIME intervention, namely improved health, social and economic outcomes in people living with the priority mental disorders in the selected districts of PRIME. The workshop participants identified the anticipated short, medium and long term goals required to achieve the impact across the three levels of the health system. The outcomes were identified in the following domains: political buy-in, programme resources, capacity building, identification and diagnosis of mental disorders and service delivery. Participants also identified assumptions and gaps in knowledge which informed the development of the formative research questions to develop contextualised MHCPs in each district. The ToC was then refined and modified by members of the PRIME consortium over the following year. An abridged version of the ToC showing the outcomes only is illustrated in Figure 3.2. The overarching cross country process of ToC development in PRIME, the resulting ToC map and the influence of the ToC on the PRIME cross country evaluation design will be described in detail in a subsequent paper.

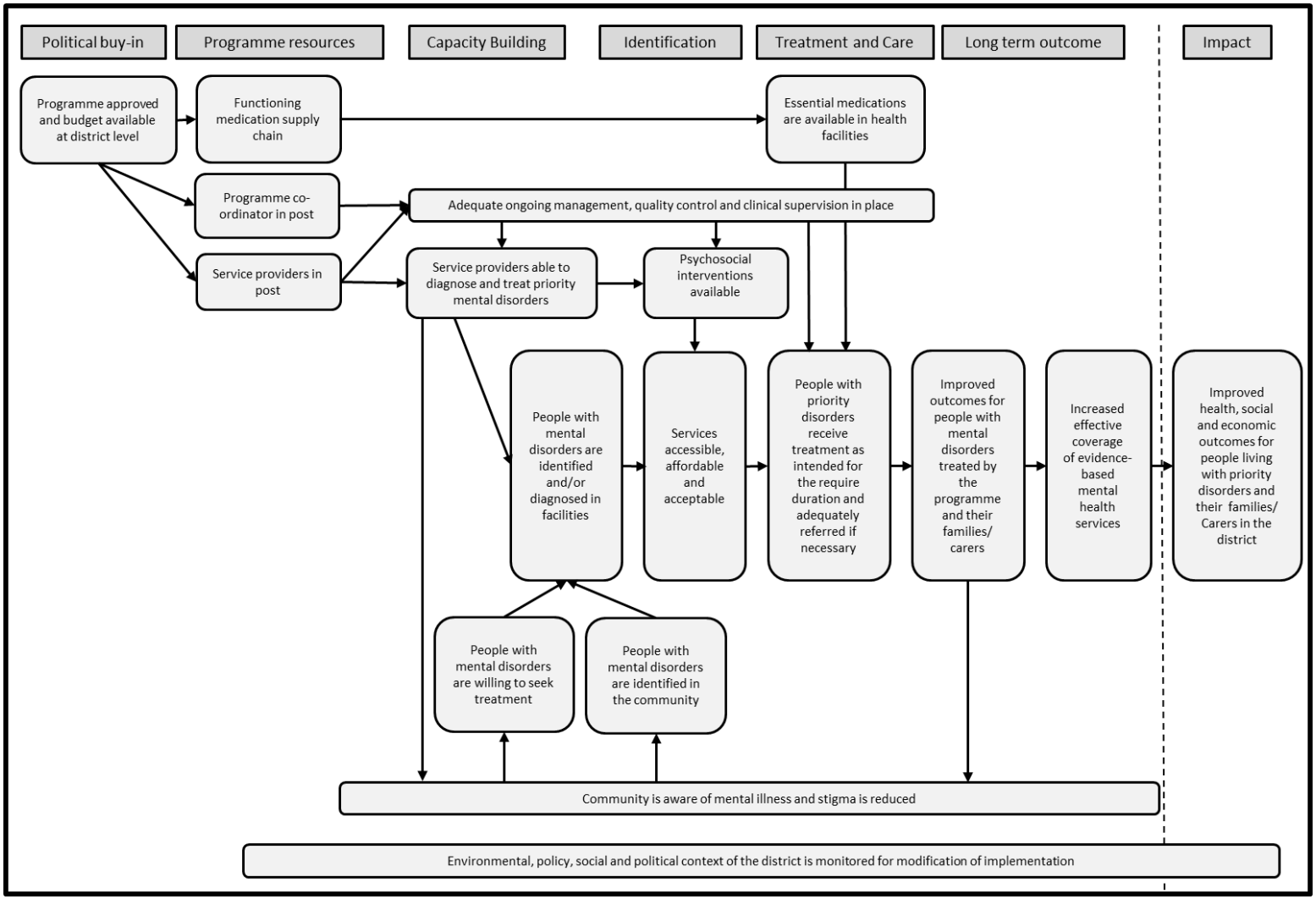

Figure 3-2 An abridged version of the outcomes and impact of the PRIME Cross Country Theory of Change.

Following this, each PRIME country team conducted at least two ToC workshops to assist with the development of the district specific ToCs. These workshops aimed to: 1) develop a logical evidenced based ToC, 2) inform the development of a contextualised mental health care plan; and, 3) to garner the buy-in of key stakeholders. The resulting ToCs were used as a 'blueprint' for the PRIME MHCPs which were developed further using results of the PRIME situational analysis, formative work, costing tool and literature reviews. The ToCs were used to validate and expand on the PRIME cross country ToC which was used as a framework to evaluate the effectiveness of the plan following implementation. The structure, number, composition and process of the workshops was determined by PRIME country teams in line with brief cross country guidelines in conjunction with Andersen's guidelines (Andersen 2004).

Stakeholders were defined as those involved in the implementation of the program, served or affected by the program or using the evaluation results (Centers for Disease Control and Prevention. Office of the Director 2006). They were purposively sampled and recruited at the discretion of country teams who aimed to balance a productive workshop with the hierarchical nature of their respective health systems. Participants included diverse stakeholders such as district health service managers, primary health care service providers, district mental health coordinators, members of the community leaders, mental health specialists, national level policy makers and mental health service users.

3.3.2 Data collection and tools

Data about the ToC workshops were collected from a number of sources. First we collected process documentation from all workshops produced by the PRIME country teams in English. This included minutes or workshop reports which reported on the key content and structure of the workshops and participant lists.

Secondly, we conducted 5 individual and 5 joint semi-structured interviews with 9 facilitators of the ToC workshops (4 principal investigators and 5 project co-ordinators) following both the preliminary and final workshops. The decision to conduct joint interviews with 2–3 facilitators from one country, or individual interviews, was made by country principal investigators. The interviews were designed to elicit the facilitators' experiences of the workshops and stimulate discussion on the practical aspects of how the workshops were conducted namely the structure of the workshop, stakeholder composition and relative contributions, the development of the MHCP, stakeholder buy in, the usefulness of the process and to generate lessons for future use in intervention development.

All interviews were telephonically or face-to-face conducted by the first author (EB) in English and transcribed by a professional transcriber familiar with health research. The transcripts were checked for accuracy by EB. Additional information was gained through email correspondence, informal discussions and presentations at PRIME consortium meetings as well as direct experience of the workshops by co-authors.

3.3.3 Data analysis

A framework analysis approach was used to analyse the process documentation and interview transcripts (Ritchie and Spencer 1994). This method was developed for applied policy research and contains five key stages: familiarisation, identifying a thematic framework, indexing, charting, mapping, and interpretation. Qualitative data software, NVivo9, was used to assist with the analysis (QRS 2011).

Following familiarisation with the process documentation and interview transcripts, a coding framework was developed by EB based on the semi structured interview guide. The main themes included workshop structure, participants and their contributions, ToC development and the contribution to the MHCP, stakeholder contributions and buy-in, and emerging themes, such as the influence of hierarchy within the health system. A framework matrix was generated using the themes: workshop structure; participants and dynamics; and their 25 subthemes which mapped onto the X axis of a spreadsheet. The 13 ToC workshops were mapped onto the Y axis. The coded data in each cell were summarised to reflect the content. The data within each column or sub-theme was compared across ToC workshops and interpreted. As the data were compared additional salient themes emerged. Following the main analysis by EB, the results were summarised and validated by co-authors who were part of the country workshops.

The study was approved by the Human Ethics Research Committee of the Faculty of Health Sciences at the University of Cape Town (REC Ref:247/2013). Ethical approval for the PRIME research programme has also been obtained by local ethics committees in study countries.

All those who participated in the semi-structured interviews gave informed consent to participate.

3.4 Findings

Between two and four ToC workshops were held in each country at different levels of the health system to develop ToCs for the PRIME district site, with a total of 13 workshops across the 5 countries. Table 3.2 outlines how each workshop was structured and Table 3.3 describes the stakeholders who participated in the workshops. More detail about the structure, stakeholders and how the workshops were conducted to achieve their multiple goals are described in subsequent sections.

Table 3-2 Summary of PRIME ToC workshops

Country	Level	Location	Length	Structure
Ethiopia				
Workshop 1. (ET1)	Community and district level representatives	Sodo*	½ day	a Introduction to PRIME
				b Explanation of the ToC process
				c Agreement on impact
				d Worked forwards to development of the ToC discussing current services, needs and potential outcomes of the ToC to reach the desired impact.
Workshop 2.(ET2)	National level planners	Addis Ababa	1 day	a Introduction of Ethiopian mental health strategy by national ministry of health representative
				c Introduction to ToC and the ToC process
				c Review and refinement of the ToC developed in ET1.
India				
Workshop 1. (IN1)	District and health Facility	Sehore*	1 day	a Introduction to mental health and PRIME
				b Introduction to ToC
				c Mental health presentation
				d Group work where each group developed the outcomes pathway for the ToC
				e Feedback from group work
Workshop 2. (IN2)	District and health Facility	Sehore*	1 day	a Summary of IN1
				b Group work: details of interventions and assumptions at community, health facility and

				health organisation level in the existing ToC map.
				c Presentation and discussion of the integrated mental health care plan developed from the ToC.
Nepal				
Workshop 1. (NE1)	Health Facility and District	Chitwan*	1 day	a Introduction to PRIME
				b Introduction to ToC
				c Agreement on long-term impact and worked the group agreed on the long term impact then worked backwards to determine the outcomes, interventions and assumptions needed to achieve this.
Workshop 2. (NE2)	National level planners	Kathmandu	½ day	a Introduction to PRIME
				b Introduction to ToC
				c ToC from NE1 was presented, reviewed and refined by the group.
Workshop 3. (NE3)	Health Facility and District	Chitwan*	½ day	a Review of the ToC developed in NE1 and NE2
				b Discussion of potential adaptation for specific disorder and indicators to measure outcomes.
Workshop 4. (NE4)	National level planners	Kathmandu	½ day	c Review of the ToC refined in NE3
				d Discussion of potential adaptation for specific disorders and indicators to measure outcomes.
South Africa				
Workshop 1. (SA1)	Health facility, district, provincial and national	Dr Kenneth Kaunda*	2 days	a Introduction to PRIME
				b Introduction to ToC

	level representatives			c Used part of the PRIME cross country ToC and worked forward adding detail to each outcome for all four disorders.
Workshop 2. (SA2)	Community	Dr Kenneth Kaunda*	1 day	a Introduction to PRIME
				b Introduction to ToC
				c Used part of the PRIME cross country ToC and worked forward adding detail to each outcome for all four disorders.
Workshop 3. (SA3)	Health facility, district, provincial and national level representatives	Dr Kenneth Kaunda*	1 day	a SA1 workshop was reviewed briefly.
				b Disorder specific integrated mental health care plan based on SA1 was presented and discussed in detail.
				c PRIME evaluation plan and next steps were discussed.
Uganda				
Workshop 1. (UG1)	District and health facility level	Kamuli*	1 day	a PRIME, mhGAP, challenges for mental health care and the ToC were introduced.
				b The impact was agreed on and the group worked backwards to develop the ToC.
Workshop 2. (UG2)	District and health facility level	Kamuli*	1 day	a The group was oriented to the ToC process, PRIME and planned work.
				b The ToC map from UG1 was reviewed and refined.

Locations marked with * indicate the PRIME district in the respective countries.

Table 3-3 Number and category of workshop participants in the ToC workshops

Country	**Ethiopia**		**India**		**Nepal**				**South Africa**			**Uganda**	
Abbreviation	**ET1**	**ET2**	**IN1**	**IN2**	**NE1**	**NE2**	**NE3**	**NE4**	**SA1**	**SA2**	**SA3**	**UG1**	**UG2**
Number of participants	17	13	20	17	14	10	11	8	38	26	37	22	22
Category of stakeholders													
1. Policy makers													
National* Health representatives		*X				X		X	X*		X*	X*	X*
State/province Health representatives			*X	*X					X		X		
2. District level planners and management													
District Health representatives													
Health planners/managers	X	X	X	X								X	X
District Medical officers			X						X		X		
MH coordinators				X	X		X		X	X	X		
Other health coordinators					X		X		X			X	X
Other district administrative or finance staff	X											X	X
Other district representatives (Justice, Education)	X												
3. Specialists													
Psychiatrists	X*	X	X	X	X		X	X	X		X		
Psychologists			X	X	X	X	X	X	X		X		
Psychiatric clinical officers												X	X
Psychiatric nurses						X						X	X
Other Medical Specialists									X		X		
4. Service providers													

Community health center, primary health center and sub health posts														
Clinic managers									X		X			
Medical officers			X	X	X		X		X		X			X
Clinical officers												X		
Health Assistants					X		X							
Nurses					X		X					X		
Lay Health workers (clinic based)					X		X		X	X	X			X
Lay Health workers (community based)											X			
Other clinic staff			X	X								X		
5. Researchers														
PRIME	X	X	X	X	X	X	X	X	X	X	X	X	X	
6. Community and civil society														
NGO/development organisations	X		X	X		X		X	X	X	X			
Community														
Community leaders	X										X			
Media		X												
Faith leaders	X									X				
Traditional healers										X				
7. Mental Health Service users														
						X		X		X				

*Members of the PRIME Consortium.

3.4.1 ToC Workshop structure

The ToC workshops were structured to include a welcome, a brief introduction to PRIME, a discussion on mental health (in some cases this was discussed in a pre-workshop meeting) and an introduction to the ToC approach. In India, Uganda and Ethiopia, the workshops were introduced by state or national Ministry of Health representatives.

Most countries started from the impact and worked backwards to map long, medium and short term outcomes required to achieve the impact. When developing the initial TOC map, workshop participants in all countries except South Africa developed a generic ToC map for mental illness rather than developing separate ToCs for each priority disorder (depression, alcohol use, psychosis and epilepsy). This was because the workshop facilitators hypothesised that the causal pathway through which the integration of mental health into primary care leads to improved outcomes were essentially the same for different disorders. The generic map was then compared and modified for the different disorders with very few changes needed for the specific disorders.

3.4.2 Stakeholders

The stakeholders were selected using a variety of criteria including: 1) involvement in planning or implementing the PRIME MHCPs at various levels including providing specialist care, co-ordinating services, providing primary care services, managing facilities or developing and evaluating the MHCPs; 2) membership of PRIME Community Advisory Boards who provide an oversight function to PRIME at district level; 3) specialist knowledge

of mental health; 4) representatives of service users or other sectors in the wider community; or 5) decision making power or control over resources.

The size of the workshops varied considerably across countries with a median of 15 (Interquartile range 13 – 22) stakeholders attending each workshop (Table 3.3). Most countries held preliminary and final workshops with the same group of people, comprising stakeholders at different levels of the health system (Table 3.2) with the exception of Ethiopia where their first workshop included district representatives and the second national level representatives and mental health specialists. Some countries, such as Uganda, India and South Africa relied on key individuals to assist with the identification of participants. These were often the District Medical Officers who assisted by inviting the participants to the workshop and thus providing the workshop with local legitimacy.

The stakeholders attending the workshops varied by country and by workshop (see Table 3.3). However, five key groups of stakeholders attended all workshops: policy makers; district level health planners and management; mental health specialists; researchers; and service providers. These groups were not mutually exclusive and many stakeholders belonged to more than one category. Some countries also had representation from community or non-governmental organisations (NGOs) but there was very little mental health service user representation with only 3/13 workshops including mental health service users.

A major potential barrier to stakeholder participation in the workshops was the hierarchical nature of local health service organisation which would have inhibited participation by

lower level staff. Consequently, the PRIME country teams who facilitated the workshops attempted to mitigate the effect of the hierarchical structures by stratifying the workshops and holding separate workshops at different levels of the health system or by limiting the levels of the participants in the workshops. For example, the Nepalese and Ethiopian facilitators stratified their workshops into district and national level workshops while South Africa held a separate workshop at the community level. Indian facilitators specifically chose to limit their workshop to district level and senior facility level in order to prevent power differentials and to optimise planning. According to one of the facilitators, this resulted in everyone "*participating because there was no hierarchy, they were all district level, all sub district level officers*". This is in direct contrast to the start of the workshops where senior district and state level stakeholders were asked to open the workshop: *"when the four of them were in the room, I think no-one was speaking anything, they cannot, I mean even if they wish to they cannot speak… once all these four people were out and then all of a sudden everyone was speaking*."

3.4.3 Achieving the goals of the TOC workshops

The ToC workshops had 3 main goals: development of a ToC map to reflect the structure of the proposed district MHCP; contextualisation of the MHCP; and ensuring the engagement and buy-in of key stakeholders to the MHCP. We reflect on how these goals were achieved below.

1) The development of a structured, logical and evidence-based ToC map

The ToC workshops helped to develop a structured and logical ToC which was described by facilitators as a "*visual map*" which, "*like a map of the city*"*,* they could refer to when thinking about their MHCP.

In four of the five countries, the ToCs were developed during the workshop with stakeholders agreeing on the intended impact of the PRIME MHCPs and then working backwards to determine the outcomes needed to achieve this impact. In South Africa, instead of developing a ToC from scratch, facilitators used the basic building blocks of the cross country ToC to initiate the discussion. They asked stakeholders to comment on the validity of this ToC and then used this to elicit more detail from the stakeholders.

Facilitators reported the process of working with the group to map out the long, medium and short term outcomes which helped to reach consensus as they had to work with stakeholders to "*refine and redefine and,… eventually agree*". It also encouraged facilitators and stakeholders to focus on outcomes rather than interventions. This was a change from usual practice, as one facilitator from India observed: "*most of us in the field of development… or public health [are] very focused on … interventions and activities"*. Assumptions underlying the ToC maps were discussed in all countries, however the primary focus was, as a Ugandan facilitator noted, more *"on the process and the outcome more than… the assumptions*".

The rationale, or evidence base, underlying the pathways on the ToC map, and the indicators used to determine success, were seen as the domain of the researchers. When

the rationale was discussed, it was only in relation to whether interventions would be required. Most facilitators thought that sourcing the evidence base underlying the ToC was the role of the researchers, as a Ugandan facilitator noted, "*because, that's about literature, evidence, and that is for us really".* Similarly, some countries discussed indicators in their final workshop, however, this was seen as something which was more important for the researchers: *"it's very important for [the researchers] to know that everything has been covered and to be able to evaluate the plan using indicators"* although it may not be *"necessary for everyone who was attending that ToC workshop".* Therefore many country teams added the indicators once the workshops were completed.

The planned interventions were discussed in all country workshops. Some countries focused on this in detail and added additional elements to the ToC workshops. In India, South Africa and Ethiopia, facilitators probed more into the resources required to implement the MHCP and the roles and responsibilities of service providers in the intervention. As one South African facilitator explained,

"*using the TOC process is really important …… in order to be able to enact the TOC plan, we need these resources in place and this is what each of these resources are going to be doing and this is how we're going to capacitate them in order to fulfil their roles and responsibilities*."

This was particularly important in many PRIME countries as no new human resources were being made available to implement the plan, apart from those already available in the district.

In South Africa and India, facilitators provided additional detail during the final workshops by presenting an integrated mental health care plan based on the preliminary ToC workshops. A facilitator from India noted that *"participants were very happy to see that what they had done, in the first workshop… came out in a very refined manner and very systematic manner".* A South African facilitator reported a similar experience,

"*we came on board with stuff that people had already discussed and agreed on and there was some clarifications that were made, a few additions that were made and in essence when we came to the workshop, there was already agreement that had been reached with the previous workshop so this is just consolidating what we had on paper and I felt that everybody was moving in the same direction*".

2) Contextualising the mental health care plans

The second purpose of the workshops was to ensure that the ToC and the MHCP were contextually relevant. During the workshops, the researchers gained contextual knowledge in several domains including the functioning of district health services, planning for mental health programmes, physical resources, medication provision, human resources, stigma, cultural understanding of mental illness and the existing community structures.

Stakeholders identified challenges, needs and potential solutions. For example, the provision of psychotropic medication was identified as a challenge in the Nepal district level workshop. Although a steady supply of psychotropic medication is necessary for effective treatment of severe depression and psychosis, no antipsychotic medications are on the free drug list and supply of medications is irregular with frequent stock outs. Policy makers at the

national level workshop were able to provide potential solutions to this problem including agreeing to provide psychotropic medications in the area of implementation of the PRIME MHCP and suggesting that additional stock is ordered as a buffer and procurement processes for emergency supplies are put in place. Similarly, during the final workshop in South Africa, stakeholders identified the need for psychologically trained supervisors for lay counsellors providing psychosocial interventions. They suggested that intern psychologists could be made available in the short term with a long term view to lobby the Department of Health to create new posts for graduates with a Bachelor of Psychology in Counselling degree (BPsych Counselling).

3) Obtaining stakeholder buy-in

The third purpose of the workshops was to obtain buy-in from the stakeholders on the ToC and MHCPs. As one facilitator remarked, one can *"have a beautiful TOC map but if [one doesn't] have the buy-in and … the various human resources available to make it work it's not… going to work".* Buy-in was achieved through the process of developing the map in consultation with stakeholders. This resulted in a sense of ownership where "*the people who were there in both the workshops feel that it's their product*". This buy-in, where "*the district has owned the theory of change",* was felt to be an important contribution of the workshops. A South African facilitator noted, *"the most important thing to derive from that second workshop was to get consensus and agreement from particularly the decision makers about who would do what… we need people to buy into…these new roles and responsibilities because it does mean quite a shift."* However, facilitators noted that this buy-in may not be achieved if used to cover a larger population. One facilitator from India cautioned that *"a lot*

of effort need to be taken before theory of change can be used as a routine tool for scaling up of programme planning".

There was general recognition that buy-in was necessary from those who were in "*positions of decision making and affect availability of services and resources".* But, as a Ugandan facilitator noted, this buy-in may be that of individuals who "*may not have the power or the political will to change what you need changed*." One facilitator cautioned that it was important to have "*both a top down and bottom up approach*" where "*political credibility*" was provided by national and state representatives and service providers "*being part of that process was really important"* so that they could *"see that it will actually be part of their work that they do*." However, it was often not possible to have all stakeholders present.

3.4.4 The contributions of stakeholders to the goals of workshops

The five key groups of stakeholders who contributed in each country to at least one of the workshops (mental health specialists, researchers, policy makers, district level health planners and management, and service providers), contributed in different ways to achieve the three goals of the ToC workshops.

Mental health specialists and researchers provided details on technical issues such as functioning of existing mental health care provision in the district, the need for prioritisation of additional disorders (such as epilepsy in Nepal) and the provision of feasible and evidence based interventions. The researchers, who were facilitating the workshops and were often also mental health specialists, provided the technical knowledge of the ToC process to develop a logical evidence based map. They also provided much of the evidence base

underlying the interventions and the indicators for the ToC which were often developed after the workshop.

The policy makers and national level planners made higher level contributions on the structure of the MHCP and possible solutions to issues such as medication procurement in Nepal and supervision structures in Ethiopia. They did not provide much additional information on the structure of the ToC map or the details of the MHCPs when separate policy maker workshops were held in Nepal and Ethiopia as these had been provided in the district level workshops: *"there wasn't much when it comes to high level …there weren't many changes from the first one, it was like… reaching a point of saturation*." Buy-in from policy makers both prior to and during the workshops was essential as they control resources, for example "*they are responsible for planning all … health care"* and *"allocate budget and programme in government health system*." The support of policy makers, who often introduced the workshops when countries only held them at one level, was seen as a way of legitimizing the PRIME project and the ToC workshop. They provided "*political credibility*" and, in some cases such as India and Uganda, were the reasons the facilitators felt that the workshops were so successful.

District level health planners and management were the main contributors to developing the overall structure of the ToC map in most of the workshops as well as providing contextual information on what they felt could or could not work. This included identifying current challenges, needs and potential solutions. For example, in Nepal they identified constraints such as incentive structures for volunteers and medication shortages, whereas stakeholders in Uganda identified the low priority of mental health and the stigma towards

service providers who work with people with mental illness. In the South African and Ethiopian workshops they identified additional community workers who could potentially be utilised for PRIME.

Service providers assisted with providing detailed information about the context and the functioning of existing systems including current workloads of personnel. As such they could comment on their ability to take on additional tasks envisaged by the MHCP. As described above, their input and buy-in was seen as essential as they would predominantly be providing the services outlined in the MHCP.

The contribution of stakeholders to the workshop was moderated by the presence of other stakeholders who were considered higher up in the health system hierarchy. This depended on the strength of the hierarchy which was considered particularly strong in Nepal and India. This led a facilitator from India to remark that the *"idea that ToC could involve everyone from health policy makers to planners to providers to community health workers in one session…needs to be kind of retested because it cannot be participative in government structures which run on hierarchy"*.

3.5 Discussion

In this study, we describe how district specific ToC workshops were used to plan for the integration of mental health services into primary health care in five low resource settings. Comparing workshops across the five countries working in PRIME has allowed us to distil some key lessons on the use of ToC workshops for complex mental health intervention development and reflect on these in relation to existing literature.

Workshop facilitators reported that ToC workshops provided a useful approach to developing a logical structure for mental health plans and provided contextual details for implementing these in district sites and obtaining stakeholder buy-in. The participatory nature of the ToC workshops allowed stakeholders to work together in a structured forum to map out the ToC for the district and creating a forum for knowledge exchange and dialogue about needs and potential solutions.

In this process, the power relationships between the stakeholders was critical, as confirmed by previous research that shows that all actors within health services can exert different power over implementation of health policy (Lehmann and Gilson 2013) and that service providers may choose to exercise this power to both promote or hinder implementation (Sheikh and Porter 2011). Therefore the active participation and buy-in of all stakeholders is likely to increase the chances of successful implementation (Gilson 2012). This is particularly important in the context of mental health services in LMIC where stigma is high (Thornicroft, Brohan et al. 2009), human resources for health are limited (Kakuma, Minas et al. 2011), funding is minimal (WHO 2011) and political priority is low (Saraceno, Van Ommeren et al. 2007).

From the outset it was clear in some countries that hierarchies within the health system would make it difficult for district level planners and service providers to participate despite using facilitation techniques. As their input was seen as essential to the process of the development of the ToC and contextualising the MHCP, country teams used various strategies to mitigate these hierarchies. These included: 1) stratification of stakeholders by having separate workshops for service providers and for policy makers; 2) limiting

participants to a homogenous group of stakeholders; or 3) seeking high level buy-in in other forums, for example, interviews. Although these strategies seem to have increased participation, the ToC is no longer 'owned' by all potential stakeholders as is recommended by the Aspen Institute (Aspen Institute 1997). This is similar to the finding by Sullivan and Stewart (2006) that it may not always be feasible to achieve total ownership of a ToC where all stakeholders are involved in the planning and development of a ToC. They propose that ToCs may be owned by different groups of stakeholders including the evaluators, by a dominant stakeholder, the community or an elite group of implementers.

Other aspects of the ToC process also reduced the ownership by all potential stakeholders such as the lack of beneficiaries of the program as well as the finalisation of the ToC by the PRIME researchers. Mental health service users were present in only 3 of the 13 workshops. Although most facilitators would have liked to have included mental health service users as beneficiaries of the programme who can provide an alternative perspective on mental illness and care (Tait and Lester 2005, Kleintjes, Lund et al. 2010) they were not included in most workshops because there are currently limited or non-existent mental health services in PRIME district sites and no active advocacy groups for mental health service users (Hanlon, Luitel et al. 2014). PRIME researchers were involved in finalising some aspects of the ToC after the workshop such as the rationale and indicators without involving the whole group of stakeholders included in the ToC. Therefore, despite including quite a broad range of stakeholders (see Table 3.3), the ownership of the ToCs in PRIME countries most closely resembles what Sullivan and Stewart (2006) refer to as elite ownership of the ToC: ownership by a small group of leaders including community leaders who are involved in setting up and implementing the program. Sullivan and Stewart (2006) propose that the ToC

process might still be effective as these stakeholders often have access to significant resources needed to support and implement wider systematic change.

It is difficult to ascertain post-hoc whether it would have been possible in these settings to run a workshop with all identified stakeholders or how the stakeholder composition of the workshops has affected the resultant quality and validity of the ToC. Certainly, the inclusion of multiple levels of stakeholders in the ToC workshops enabled a combination of top down and bottom up approaches to planning by either acting as a structured forum for discussion where all stakeholders participated in the same workshop or as a conduit between policy makers and service providers where workshops were stratified. The ToC workshops enabled district level stakeholders to directly influence the planning process which was then vetted by the policy makers who agreed to implement the plan. Undoubtedly the initial success PRIME has had in facilitating the bottom up planning process was directly influenced by the participation of Ministry of Health partners in the consortium formalised through Memoranda of Understanding and on-going policy engagement (Lund, Tomlinson et al. 2012, Hanlon, Luitel et al. 2014). However, it is yet to be established whether this participatory process has resulted in real ownership of the MHCPs on the ground by service providers and a real increase in resources from senior policy makers.

A key limitation of the workshops was the lack of explicit focus on the assumptions underlying the ToC in the workshops. Assumptions are seen as one of the core elements of ToC which allow stakeholders to ensure that they understand each other's perspectives (Vogel 2012). These were not covered in detail, as the facilitators wanted to focus more on the outcomes and interventions and felt the assumptions may have been too complex for

some of the stakeholders. However, the rich discussions reflected in the content of the workshops indicated that assumptions did emerge during the discussions between stakeholders.

There were several shortcomings of this study. First, our sample size was small and we focused only on the experiences of workshop facilitators, both in the interviews and in the process documentation produced by research teams. Some of these facilitators were also included as authors on this paper and the remaining authors were involved in supporting the facilitators in conducting and refining their ToCs. This may result in a biased view of the ToC workshops and an overestimation of their usefulness. In future it would be important to gauge the extent of buy-in from other stakeholders and examine this with the ToC process over the course of the project to determine the impact of the long term influence of the ToC process. Secondly, we did not explicitly examine the power relationships within the workshops. For example, the researchers may have been seen as powerful "experts" within the field which may have prevented frank discussion amongst stakeholders and a social desirability bias in the workshop participants. Thirdly, we did not explore the roles and contributions of mental health service users to the ToC process which are likely to have been different from other stakeholders. Finally, this paper focused on a small aspect of the ToC process within PRIME, namely the district specific ToC workshops. A more detailed description and analysis of the overall ToC process within PRIME, including the role of the ToC in the development of the PRIME MHCPs and the evaluation design is necessary and planned in a subsequent paper. Despite these limitations, we were able to draw a rich comparison of experiences across countries who had quite similar experiences across

settings and draw on some key lessons for conducting ToC workshops within the health system in LMIC.

1. The goals of the workshops should be clearly stated prior to the workshop. This should include a statement about the level of detail required in the workshops and resulting ToC, as well the ideal ownership of the ToC and potential limitations thereof.

2. The number, length, structure, components of the ToC and stakeholder composition should be flexible and adapted to ensure the ToC workshops can meet the stated goals within the context.

3. Facilitators need to be aware of the health system hierarchies and composition of workshops should be balanced to manage these using facilitation or stratification to ensure the ToC can meet the stated goals.

4. Additional strategies such as individual interviews or reviews of the resulting ToCs may be necessary to involve stakeholders not included in the workshops to ensure broader ownership of the ToC.

5. The support of policy makers is important throughout the process to add legitimacy to the workshops and increase the likelihood of implementation of the resulting MHCP.

3.6 Conclusions

This study has shown how ToC workshops can be conducted to develop ToCs as a basis for contextualised district level MHCPs and to facilitate stakeholder buy-in. The ToC workshops

in PRIME demonstrated that different stakeholders contribute different perspectives to the planning process and although a wide range of stakeholders should be included, hierarchical health systems may limit the participation of all stakeholders in the workshops. Various strategies may be required to mitigate these effects to achieve the stated goals of the workshops. However, these may limit the ownership of the ToC.

3.7 Declarations

3.7.1 Funding

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Chapter 4. Planning and evaluating mental health services in low- and middle-income countries using Theory of Change

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4.1 Abstract

4.1.1 Background

There is little practical guidance on how contextually relevant mental healthcare plans (MHCPs) can be developed in low resource settings.

4.1.2 Aim

To describe how Theory of Change (ToC) was used to plan the development and evaluation of MHCPs as part of the Programme for Improving Mental Health Care (PRIME).

4.1.3 Methods

ToC development occurred in three stages: (a) development of a cross-country ToC by 15 PRIME consortium members; (b) development of country specific ToCs in 13 workshops with a median of 15 (IQR 13 –22) stakeholders per workshop; and (c) review and refinement of the cross-country ToC by 18 PRIME consortium members.

4.1.4 Results

One cross-country and five district ToCs were developed which outlined the steps required to improve outcomes for people with mental disorders in PRIME districts.

4.1.5 Conclusions

ToC is a valuable participatory method which can be used to develop MHCPs and plan their evaluation.

4.2 Background

Despite growing recognition that mental health services should be integrated into primary care substantial constraints to integration exist in low- and middle-income countries (Thara, John et al. 2014). These include competing public health priorities (Saraceno, Van Ommeren et al. 2007), low investment in mental health services (World Health Organization 2011), a paucity of specialist human resources (Kakuma, Minas et al. 2011) and resistance to decentralisation (Saraceno, Van Ommeren et al. 2007). There is also little practical guidance on how planning for integrated mental health services can be achieved. The WHO Mental Health Policy and Service Guidance Package (World Health Organisation 2005), for example, provides overall guidance on the steps to follow in the development of mental health policies and plans but does not provide detail on how this can be done in practice to develop contextually relevant mental healthcare plans.

As part of the Programme for Improving Mental Health Care (PRIME) we used Theory of Change (ToC) as an approach to developing integrated mental health care plans (MHCPs) for specific districts in Ethiopia, India, Nepal, South Africa and Uganda (Lund, Tomlinson et al. 2012, Hanlon, Luitel et al. 2014). Using PRIME as a case study, this article describes how ToC was used as a planning tool for the development and evaluation of the PRIME MHCPs

and provides a framework which can be adapted for use in the development of MHCPs in low resource settings.

4.3 Methods

4.3.1 The Theory of Change approach

ToC is a theory-driven approach to programme design and evaluation which starts by making explicit a theory of how a programme will achieve its impact by describing the hypothesised steps along the causal pathway and uses this theory to guide the evaluation of the programme (Connell and Kubisch 1998). It has been used to design and evaluate complex programmes (Cole 2003, Mason and Barnes 2007, Weitzman, Mijanovich et al. 2009, Coryn, Noakes et al. 2011, Vogel 2012), including systems of mental health of care for children (Hernandez and Hodges 2006). However, based on preliminary results of a systematic review conducted by the authors, there are no reported examples in the literature of how it can be used for the development of mental health services in low- and middle-income countries.

The defining feature of a ToC compared to the logframe or logic models (Vogel 2012) is that ToC organises the short, medium and long term outcomes necessary to achieved the impact outcome onto a causal pathway, or ToC map (Andersen 2004). This impact is the long term vision of the programme and will often occur long after the programme is completed (Blamey and Mackenzie 2007). The activities or interventions required to move from one

outcome to the next are mapped onto the causal pathway. The evidence base or rationale for each link in the causal pathway is made explicit, usually based upon literature reviews or the tacit knowledge of implementers. Assumptions about the conditions under which the ToC will work are articulated as part of the ToC. In addition, indicators are developed for each outcome along the causal pathway in order to measure progress. The ToC approach is purposefully method-neutral and does not prescribe the types of evaluation designs which are used to collect the indicators for the ToC (Connell and Kubisch 1998).

Ideally, a ToC should be developed during the planning stages (Connell and Kubisch 1998) of a programme using various methods: reviews of programme documentation, interviews with stakeholders and/or stakeholder workshops (Mason and Barnes 2007).

4.3.2 The Theory of Change Development Process in PRIME

We used a ToC approach as one of the methods to develop the PRIME MHCPs. This occurred in three overlapping stages (Table 4.1). The first stage involved the development of an initial cross-country ToC at a workshop in India in November 2011, involving 15 key PRIME partners including psychiatrists, psychologists, epidemiologists, programme managers and at least two people who were experienced in mental health service delivery in each of the PRIME countries.

Table 4-1 Stages of the ToC Development Process

1.	Initial Development of PRIME Cross Country ToC			Number of participants
		Nov –Dec 2011	i. PRIME Cross Country ToC workshop with key PRIME partners	15
2.	Development of District Specific ToCs			
a.	Sodo, Ethiopia	February 2012	i. Pre-ToC workshop with PRIME Ethiopia team	10
		February 2012	ii. ToC workshop with community and district level representatives	17
		February 2012	iii. Final ToC workshop with national level planners	13
b.	Sehore, India	December 2011	i. Development of trial ToC by PRIME India group	4
		January 2012	ii. ToC Workshop with district and health facility representatives	20
		April 2012	iii. ToC Workshop with national level planners	17
c.	Chitwan, Nepal	February 2012	i. ToC Workshop with district and health facility representatives	14
		March 2012	ii. ToC Workshop with national level planners	10
		March 2012	iii. ToC Workshop with district and health facility representatives	11
		April 2012	iv. ToC Workshop at national level planners	8
d.	Dr Kenneth Kaunda, South Africa	March 2012	i. ToC Workshop with health facility, district, provincial and national level representatives	38
		March 2012	ii. ToC Workshop with community level representatives	26
		August 2012	iii. ToC Workshop with community, health facility, district, provincial and national level representatives	37
e.	Kamuli, Uganda	February 2012	i. ToC Workshop with district and health facility representatives	22
		July 2012	ii. ToC Workshop with district and health facility representatives	22
3.	Refinement of PRIME Cross Country ToC			
		Dec 2011	i. Review of ToC by other PRIME members	17
		October 2012 – April 2013	ii. Review of Country ToCs and revision of Cross-Country ToC	Led by 2 consortium members with written feedback from consortium
		October 2012 – March 2013	iii. ToC and MHCP Indicator mapping	Led by 3 consortium members 3 with written input from >1 researcher from each country

The purpose of the ToC workshop was to introduce PRIME partners to the ToC approach and to develop and refine the PRIME cross-country ToC. This included mapping out the hypothesised causal pathways which comprised key outcomes and interventions necessary to achieve effective coverage of evidence-based mental health services and the ultimate impact of PRIME. The identified impact was: improved health, social and economic outcomes for people living with priority mental disorders and their families/carers in the district.

The ToC was informed by the previous work and principles of the PRIME consortium including:

1. The guiding principles of PRIME: (a) a focus on health systems strengthening; (b) working in partnership with Ministries of Health; (c) prioritising key mental disorders; (d) developing robust frameworks for the design and evaluation of complex interventions; and (e) ensuring equity (Lund, Tomlinson et al. 2012).
2. A draft framework for the PRIME MHCPs developed by the PRIME consortium at the outset of the project which outlined the three levels of the health system at which integration of mental health into primary care should occur: healthcare organisation, health facility and community based care (Lund, Tomlinson et al. 2012).
3. Work undertaken during the development of WHO mhGAP (World Health Organization 2010, Dua, Barbui et al. 2011) and the PLoS Medicine Series on packages on mental, neurological, and substance use disorders in low- and middle-

income countries (Patel and Thornicroft 2009) to identify cost effective interventions.

4. The programmatic and research experience of the PRIME partners; and a situational analysis of the PRIME districts (Hanlon, Luitel et al. 2014).

During the workshop, the participants also identified a range of assumptions required to successfully implement the MHCP. These assumptions identified the contextual conditions which needed to be in place for the MHCP to function or which might limit or facilitate the implementation of the MHCPs. These assumptions were used to identify cross-country research questions which were developed into cross-country interview guides for semi-structured interviews and focus group discussions with stakeholders and adapted for use in PRIME countries.

The second stage of the ToC process was the development of specific ToCs for each PRIME implementation districts: Sodo, Ethiopia; Sehore, India; Chitwan, Nepal (Jordans, Luitel et al. 2013);′ Dr Kenneth Kaunda, South Africa; and Kamuli, Uganda. Details regarding the characteristics of the district sites have been provided elsewhere in this series (Kigozi, Kizza et al. 2015, Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Petersen, Fairall et al. 2016, Shidhaye, Shrivastava et al. 2016). These were developed primarily using ToC workshops with stakeholders in each district, informed by Andersen's guidelines on conducting ToC workshops (Andersen 2004). The structure, content and stakeholders in the workshops have been described in detail elsewhere (Breuer, De Silva et al. 2014). In brief, between two and four ToC workshops were held in each PRIME country with a median of 15 (Interquartile range 13-22) stakeholders per including policy makers, district level health

planners and management, mental health specialists, researchers, service providers and, in some countries, service users (Table 4.1). The stakeholder composition of the workshops was determined by the PRIME country teams in order to include key decision makers and take into account the hierarchical nature of the local context. The ToC maps for each district were subsequently refined in different ways in each country by the PRIME country research teams using results of other formative work, ongoing internal meetings and meetings with stakeholders.

Following the development of the district specific ToCs, the content of the MHCPs were developed for each district (Kigozi, Kizza et al. 2015, Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Petersen, Fairall et al. 2016, Shidhaye, Shrivastava et al. 2016). The ToC was used as a framework to identify interventions which would be feasible in the setting, the human and other resources which could be used to provide these interventions, the contextual barriers and facilitating factors for implementation and the indicators to measure success. The ToC workshops provided rich discussions on many of the above issues and allowed aspects of the plan to be refined and agreed upon by key stakeholders (Breuer, De Silva et al. 2014). However, given the length of the ToC workshops and the number of stakeholders, not all details of the MHCP could be discussed and were finalised using other formative work including results from qualitative formative research among stakeholders and piloting (Hanlon, Luitel et al. 2014). For example, in South Africa, interviews with stakeholders were used to inform the cultural appropriateness and acceptability of interventions such as using HIV counsellors to provide depression counselling in a group format. Similarly in Nepal, the formative work helped to identify the types of stakeholders

who could assist with community detection. In Ethiopia, piloting the training of healthcare workers helped to determine the amount of practical time included in the training.

The third stage of the ToC process involved the refinement of the cross-country ToC. This started with a review of the cross-country ToC by key members of the PRIME consortium who were not present at the initial development workshop. The feedback was provided at a PRIME meeting in December 2011 where 17 members of the PRIME consortium were present, through individual discussions and email correspondence. In addition, we conducted a review of the district specific ToC maps to ensure that the PRIME cross-country ToC covered all the major pathways and assumptions outlined in the district ToCs. We also developed indicators for each outcome of the ToC to measure whether the outcomes are achieved. The interventions which are required for one outcome to lead to the next were mapped onto the PRIME cross-country ToC. Then we began consolidating the input, process, output and outcome indicators developed for the interventions for all five of the implementation districts. This was done by looking across all five sets of MHCP indicators and choosing key indicators which were common across the packages and could be implemented in all countries. These indicators were combined into a master list which was reviewed by the members of the consortium. Each of the indicators was operationalised and study designs were chosen which would measure these indicators. The methods used to evaluate the MHCPs are described in detail elsewhere in this series (De Silva, Rathod et al. 2016).

4.4 Results

The PRIME ToC process resulted in various outputs including six ToCs: one cross-country ToC and five district ToCs (Table 4.2). The main components of the cross-country ToC are outlined below, namely the outcomes pathway, the key interventions, the major assumptions and the indicators, with a summary ToC map illustrated in Fig. 4.1. A more detailed version of the cross-country ToC can be found in Appendix 4.1.

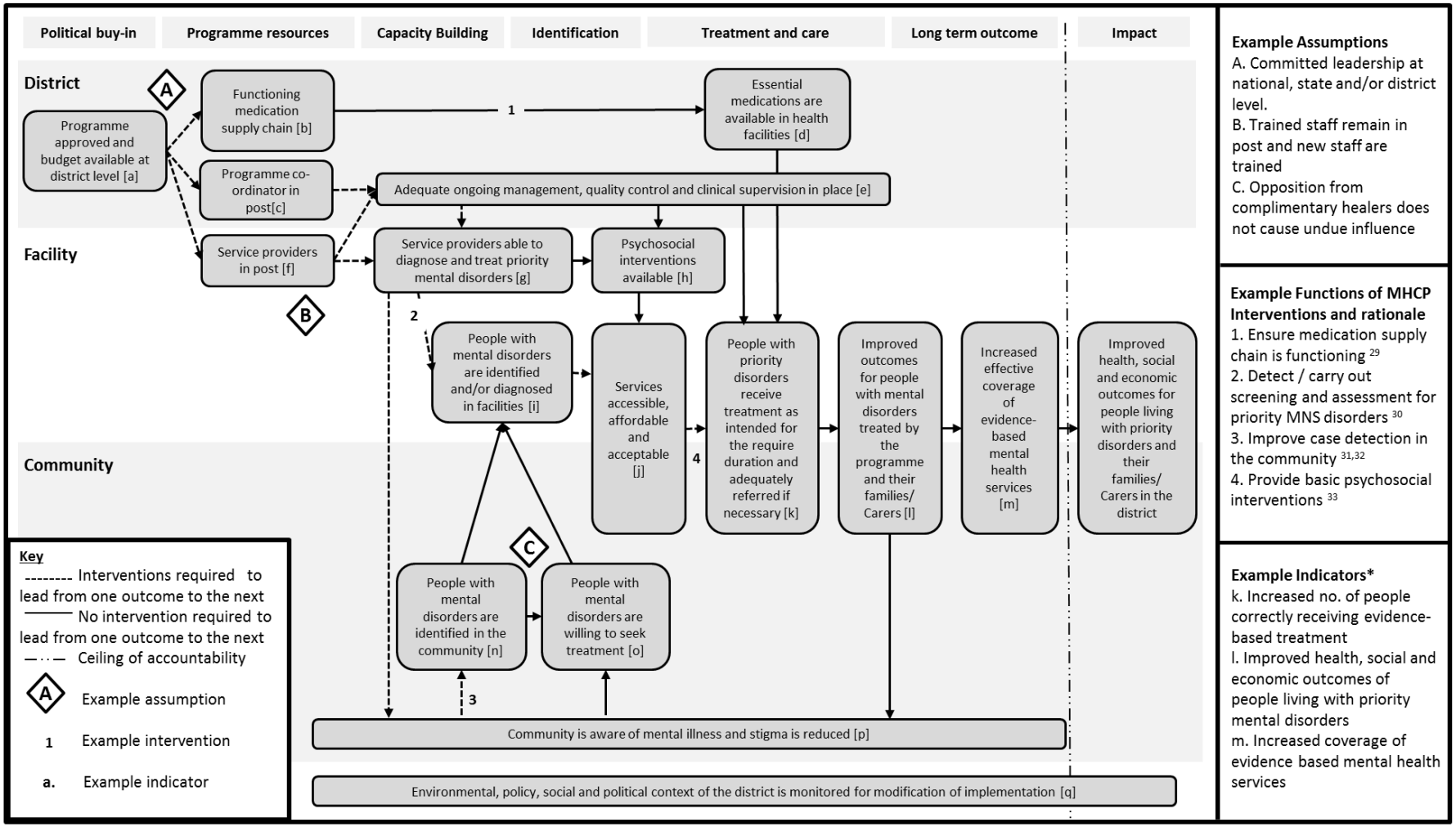

Figure 4-1 The PRIME Cross-Country Summary ToC

Following this, we describe the key differences between the cross-country ToC and the district specific ToCs which can be found in Appendices 4.2-4.6.

Table 4-2 Outputs from the ToC Development Process

Stage of ToC Development	Outputs
1. Initial Development of PRIME Cross-Country ToC	Preliminary PRIME Cross-Country ToC
	Cross-country interview guides for the individual in depth interviews and focus group discussions with stakeholders
2. Development of District Specific ToCs	District specific ToCs for Sodo,Ethiopia (Appendix 4.2); Sehore, India (Appendix 4.3); Chitwan, Nepal (Appendix 4.4); Dr Kenneth Kaunda, South Africa (Appendix 4.5); Kamuli, Uganda (Appendix 4.6)
	District specific MHCPs for Sodo, Ethiopia(Fekadu, Hanlon et al. 2016); Sehore, India(Shidhaye, Shrivastava et al. 2016), Chitwan, Nepal (Jordans, Luitel et al. 2016); Dr Kenneth Kaunda, South Africa(Petersen, Fairall et al. 2016); Kamuli, Uganda(Kigozi, Kizza et al. 2015).
3. Refinement of PRIME Cross-Country ToC	PRIME Cross Country ToC (Appendix 4.1)
	Outline of PRIME Evaluation Design (see (De Silva, Rathod et al. 2016) for more details)

4.4.1 The PRIME cross-country TOC matrix

The underlying structure of the PRIME ToC is a matrix, with level of the health system on the vertical axis describing where the MHCPs are implemented (community, health facility and healthcare organisation), and the temporal dimension on horizontal axis illustrating the sequence in which the MHCPs are implemented. The temporal dimension should be read from left to right and specifies the types of outcomes along the hypothesised causal pathway required to reach the desired impact (Fig. 4.1). Specifically: getting political buy-in;

mobilisation of programme resources; capacity building; identification of people with mental disorders; treatment and care; and long term outcome and impact. The short, medium and long term outcomes required to reach the impact are specified on the ToC map with the indicators for each outcome and how they will be measured described in Tables 4.3 and 4.4. The point at which the programme is no longer responsible for the outcome is delineated by a 'ceiling of accountability'.

4.4.2 Outcomes pathway

The PRIME ToC identifies political buy-in as the first step in the implementation of the PRIME MHCPs. A guiding principle of the PRIME MHCPs is full integration into the existing district health system with services provided by existing human resources therefore the approval of the MHCP by district health management is necessary for implementation. Next, the ToC identifies the importance of the availability of programme resources necessary for implementation. This includes the availability of medications through a functioning supply chain, human resources to coordinate, train, supervise and deliver services as well as a functioning health information system to measure service delivery.

The need for capacity building is identified by the PRIME ToC for service providers at three levels: specialist, primary healthcare and community. Primary and community level service providers need to be competent in the identification or diagnosis of priority mental disorders and should be able to treat or refer where appropriate as well as promoting stigma reduction and increasing awareness of mental illness. The PRIME ToC makes explicit that specialist service providers should be aware that their role in mental health services

integrated in primary care includes supervision and training in addition to direct service delivery.

Identification of people with mental disorders is a key outcome in the PRIME ToC and occurs at two levels of the health system: at the community level and at the facility level. This is followed by treatment, care and rehabilitation. For this to occur, the ToC specifies that medications, psychosocial interventions and components of community based rehabilitation need to be available at the facility and in the community. These interventions need to be acceptable, affordable, accessible, cost-effective, and people with priority disorders need to be willing to receive them. They should be delivered for the required duration and cases should be referred as necessary to other services. In order to do this, an effective interface between community, facility and specialist services is necessary. To ensure that identification, treatment and care of people with priority disorders occurs at the community and facility levels, adequate ongoing monitoring and evaluation, quality control and supervision is necessary.

If all of the outcomes described in the ToC are achieved, people living with priority disorders treated by the programme and their families or carers should have improved health, social and economic outcomes. If services were scaled up throughout the district resulting in an increase in treatment coverage of the PRIME MHCPs, the desired impact of improving outcomes for people with priority disorders in the whole district should ultimately be achieved, although this impact is beyond the ceiling of accountability for the PRIME programme.

4.4.3 Interventions

The content of the interventions required to move from one outcome to the next varies between the different district level ToCs. This reflects the reality of the MHCPs, the content of which vary between district sites due to differences in the acceptability and feasibility of the interventions that make up the MHCPs. For example, the same outcome, 'people with mental disorders are identified and/or diagnosed in facilities' is achieved through different interventions in different districts. In Ethiopia, Uganda, India, and Nepal depression is being detected through an adapted version of the WHO MhGAP (Kigozi, Kizza et al. 2015, Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Shidhaye, Shrivastava et al. 2016), while in South Africa mhGAP has been included in national integrated guidelines for chronic care at PHC level called Primary Care 101 (PC101) (Petersen, Fairall et al. 2016). Similarly, the outcome 'people with priority disorders receive cost-effective intervention(s) in the community as intended for the required duration and are adequately referred' is achieved through different interventions in each district. In South Africa this is being provided by psychosocial rehabilitation groups (Petersen, Fairall et al. 2016) whereas in Ethiopia this will be provided by individual community based rehabilitation (Fekadu, Hanlon et al. 2016). In Uganda, Ethiopia and India people with priority disorders will be referred to existing community organisations or NGOs providing rehabilitation (Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Shidhaye, Shrivastava et al. 2016). In Nepal, community counsellors will be delivering individual- and family-based psychological treatments (Jordans, Luitel et al. 2016). The content of these interventions, the supporting evidence base and human and other resources required to implement the MHCPS are detailed in other papers in this series (Kigozi, Kizza et al. 2015, Fekadu, Hanlon et al. 2016, Jordans,

Luitel et al. 2016, Petersen, Fairall et al. 2016, Shidhaye, Shrivastava et al. 2016) and compared across all five PRIME districts by Hanlon et al (Hanlon, Fekadu et al. 2016).

4.4.4 Assumptions

The cross-country ToC makes explicit several assumptions about what needs to be in place for the outcome pathway to be achieved. These include political buy-in which results in adequate funding, committed leadership at various levels and engagement of staff at all levels in the programme despite the lack of financial incentives available. For all levels of service providers, the ToC specifies that there needs to be relative stability within the human resources so that trained staff are retained or new staff are trained in order for the ToC to achieve its stated outcomes.

4.4.5 Indicators

The short, medium and long term outcomes of the ToC map roughly divide into inputs (political buy-in, programme resources) processes (capacity building), outputs (identification, treatment, rehabilitation and care) and outcomes of the PRIME MHCPs. Each ToC outcome is operationalised and measured by an indicator. For example, the outcome 'essential medications are available in a health facility' is being measured by the indicator 'medications are available at all clinics 95% of time (disaggregated by clinic and type of medication)'. 'People with mental disorders are identified in the community' is being measured by 'Increased number of cases detected and managed by CHW'.

A list of indicators for the summary ToC is shown in Table 4.3 and Table 4.4.

Table 4-3 ToC indicators at health organisation level

	ToC Outcome	Indicator(s)	Study Design
a.	Programme approved and budget available at district level	Mental health integrated into the District Health Plan % increase in financial resources allocated to mental health released on time and available to spend	Case study: district profile
b.	Functioning medication supply chain	# Stockouts in last 30 days for essential psychotropic medications outlined in the MHCP	Case study: facility profile
c.	Programme coordinator in post	Mental health programme coordinator in post prior to MHCP implementation	Case study: district profile
d.	Essential medications are available in health facilities	Medications are available at all clinics 95% of time (disaggregated by clinic and type of medication)	Case study: facility profile
e.	Adequate ongoing management, quality control and clinical supervision in place	All staff receive quality supervision on a regular basis as defined by the MHCP and guidelines	Case study: training and supervision evaluation Case study: process evaluation

Table 4-4 ToC indicators at facility and community levels

	ToC Outcome	Indicator(s)	Study Design
f.	Service providers in post	Adequate numbers of human resources as per the MHCP are available at primary and community levels	Case study: facility profile
g.	Service providers able to diagnose and treat priority mental disorders	Change in knowledge and attitudes pre- and post-training	Case study: training and supervision evaluation
h.	Psychosocial interventions available	Staff trained in psychosocial interventions are available at the facility	Case study: facility profile
i.	People with mental disorders are identified and/or diagnosed in facilities	Increased no. and proportion of people correctly identified/diagnosed with depression and alcohol use and treated with evidence based interventions	Facility Detection Survey
		Increase in % mental health case load as a proportion of total PHC headcount	Case study: facility profile
j.	Services accessible, affordable and acceptable	Service users' perception of accessibility and acceptability of services	Cohort: qualitative
			Cohort
k.	People with priority disorders receive treatment as intended for the require duration and adequately referred if necessary	Increased no. of people correctly receiving evidence-based treatment	Facility Detection Survey
		# of patient who received psychosocial interventions at community level and facility level for the required duration	Cohort

l.	Improved outcomes for people with mental disorders treated by the programme and their families/carers	Improved health, social and economic outcomes of people living with priority mental disorders	Cohort
m.	Increased effective coverage of evidence-based mental health services	Increased coverage of evidence based mental health services	Community survey Cohort
n.	People with mental disorders are identified in the community	Increased number of cases detected and managed by CHW	Case study: community profile
o.	People with mental disorders are willing to seek treatment	Increase in help-seeking and earlier presentation at clinic	Facility detection survey
p.	Community is aware of mental illness and stigma is reduced	Improved MH literacy and decrease in stigma	Community survey
		Community members are aware of local availability of treatment	
		Decreased reported stigma by people with priority disorders	Cohort
q.	Environmental, policy, social and political context of the district is monitored for modification of implementation	Changes in environmental, policy, social and political contexts are monitored throughout implementation	Case study: district profile

Four major study designs were developed to collect data for these indicators and are described in detail in this series by De Silva, Rathod et al. (2016). These include:

(a) Repeat cross sectional community surveys conducted at baseline and 24 months after MHCP implementation in four of the districts where PRIME will be implemented.

(b) Repeat facility surveys conducted at baseline, 3-6 months and 24 months after implementation of the PRIME MHCPs in all study districts.

(c) Treatment cohort for the PRIME priority disorders in all study districts.

(d) A case study in all study districts including profiles of the community, facility and healthcare organisation, qualitative process evaluation of the MHCPs, evaluations of training quality and fidelity, and costing of the MHPCs.

4.4.6 Comparison of cross-country ToC and between district specific ToCs

In general, there is a lot of similarity both between the cross-country ToC and between the district specific ToCs. Specifically, the temporal dimension of the district ToCs are similar to each other and the cross country ToC. Although not always explicitly identifying the underlying matrix as the cross-country ToC does, all ToCs identify outcomes related to political buy in, programme resources, identification of people with priority mental disorders, treatment, care and rehabilitation, and the long term outcome and impact. The vertical axis of the cross country ToC matrix, i.e., the level of implementation, are also reflected either explicitly or implicitly in all the district ToCs. There are some differences between the district ToCs in relation to the specific outcomes required to reach the impact. These are a result of the discussions at the ToC workshop and other formative work. For

example, in India, recommendations from the ToC workshop include the establishment of a dedicated mental health cell to coordinate mental health services at facility level. In Nepal adolescent depression was identified as a priority area therefore they have added an outcome requiring a functioning psychosocial support programme to be in place in schools. As discussed above, the interventions which comprise the MHCPs differ in each country based on feasibility and acceptability. These differences are also reflected in interventions outlined in the district specific ToCs.

The majority of assumptions in the district specific ToCs are similar between countries and related to issues of political buy-in, budget, the willingness and capacity of staff to participate in training and service delivery and the willingness of other organisations to provide services. However, there are some differences according to country. For example, in South Africa, where there is a relatively good supply of psychotropic medication, there was no need to intervene. Therefore, rather than including it as an outcome in the South African ToC it is listed as an assumption. The indicators used to measure success differ between countries based on the country specific outcomes, the availability of routine data, feasibility of data collection and whether these indicators are being measured as part of the cross-country evaluation design.

4.5 Discussion

The ToC approach led to the development of an underlying programme theory, highlighting the outcomes required for the integration of mental health into primary healthcare at district level. The PRIME ToC map provides a visual summary of the programme, making

explicit the hypothesised causal pathways through which the components of the MHCP interact to achieve the intended long term outcome of improved clinical, social and economic outcomes for people with priority mental disorders.

The underlying programme theory is similar across all the country ToCs and can be summarised by the cross-country ToC. We hypothesise various reasons for this. First, the development of the cross-country and district ToCs were interlinked. Facilitators from countries were involved in the conceptualization of the PRIME goals and guiding principles and the development of cross country ToC. Following the development of the district ToCs the cross-country ToC was revised to ensure that that the cross-country ToC reflected the main causal pathways outlined in the district ToCs. Second, there are similarities between PRIME implementation districts such as the low coverage of evidence based mental health services, lack of integrated mental health services at primary care level and their associated support structures, a paucity of mental health specialists and low levels of financial support for mental health (World Health Organization 2011, Hanlon, Luitel et al. 2014).

The PRIME ToCs are similar to other ToCs used to plan mental health services in which the authors are involved (De Silva, Breuer et al. 2014). ToC was used to develop a counselling intervention for maternal depression delivered by community health workers in Pakistan by the South Asian Hub for Advocacy, Research and Education on mental health (SHARE) and to develop a community based rehabilitation intervention for an RCT investigating Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE) (De Silva, Breuer et al. 2014). In both SHARE and RISE the temporal dimension of the ToC matrices are similar to PRIME, including outcomes related to programme resources, capacity building,

identification, treatment, care and rehabilitation, long term outcome and impact. As both SHARE and RISE are primarily focused at one level of the health system they do not make explicit the vertical dimension of their ToC specifying the levels of the health system. However, they do include referral to other levels of the health system within the causal pathway of their ToC. The actual outcomes along the causal pathway differ between SHARE, RISE and PRIME with SHARE and RISE providing more detailed outcomes given the more narrow focus of their programme. The similarities of these three ToCs indicate that the PRIME ToCs may capture the programme theory underpinning the provision of mental health services integrated into the health system. Therefore the cross-country ToC could be used as a heuristic device to aid the development and scaling up of mental health services in similar settings.

As described in detail elsewhere (Breuer, De Silva et al. 2014), the process of developing PRIME country ToCs through participatory workshops contributed to the development of contextually relevant PRIME MHCPs with the buy-in of a broad range of stakeholders (Table 4.1). The stepwise approach to ToC development allowed stakeholders to discuss in detail the hypothesised outcomes required along the causal pathway and ensured that the initial focus of the workshops remained on the outcomes which needed to be achieved. Although the underlying programme theory identifying the required outcomes was similar across all sites, the substance of the interventions which formed the basis of the MHCPs and details of implementation such as the cadre of human resources delivering the intervention, type and location of the intervention varied between countries. During this process, the assumptions of various stakeholders and potential challenges in implementation were explored. Brainstorming around solutions to these challenges with various stakeholders in the district

allowed local solutions to be recommended. For example, in Nepal, where the supply of psychotropic medications is erratic, policy makers suggested alternate solutions to ensure a regular medication supply. The presence of a wide range of stakeholders such as district management, planners, policy makers, service providers and researchers allowed stakeholders to work together to plan the impact they want to achieve and to ensure ownership of the MHCPs (Sullivan and Stewart 2006). Feedback from the facilitators of the workshops indicated that stakeholders were engaged in the ToC process (Breuer, De Silva et al. 2014), however it is too early to establish whether participation in the workshops led to sustained engagement in the project and support during implementation.

The cross-country ToC also provided a useful framework to develop the evaluation design for the MHCPs. Once the indicators had been identified for all the outcomes in the PRIME ToC they were operationalised into cross-country study designs (De Silva, Rathod et al. 2016). An advantage of the ToC is the focus on measuring indicators for each outcome on the ToC pathway resulting in a clear evaluation of inputs, processes and outcomes across the whole causal pathway of the intervention. This helps to unpack the black box of a complex intervention by distinguishing intervention ineffectiveness from implementation failure and assesses the relative contributions of specific components of the MHCPs to the overall outcome (De Silva, Breuer et al. 2014). As the same outcomes are being measured across all sites it allows us to compare the effectiveness of the components of the MHCPs across sites. This is particularly important for the evaluation of complex, multi-site interventions such as PRIME.

Another important aspect of the evaluation of complex interventions is the influence of context on the implementation and outcomes (Hawe, Shiell et al. 2004). The PRIME ToC makes explicit the need to measure the influence of context on achieving the pathway to impact. This is important because the contextual conditions in each PRIME country vary significantly and are influenced by other social, political and health system changes (Hanlon, Luitel et al. 2014). The Dr Kenneth Kaunda district in South Africa, for example, is well resourced compared to other countries and is a pilot site of other government led initiatives such as the introduction of PHC reengineering and an integrated chronic disease management model of care. In Sehore, India, there is the concurrent introduction of the District Mental Health Programme whereas in Sodo, Ethiopia, and Chitwan, Nepal, there are currently no major initiatives with regard to mental health. Consequently, careful documentation and analysis of context in the case study will be essential to interpret the results of the PRIME evaluation of the MHCPs.

The PRIME ToC can be used as a heuristic device which is adapted and refined to implement and scale up MHCPs in similar settings. This may increase the efficiency of the ToC process (Funnell and Rogers 2011) but may compromise the stakeholder buy-in and bottom up development of the ToC which we found in our ToC workshops (Breuer, De Silva et al. 2014). We therefore recommend that ToC workshops are still held as part of the planning process to ensure ownership of a larger group of stakeholders which may increase the chance of successful implementation (Sullivan and Stewart 2006).

Although the PRIME experience has shown that the ToC process may be useful for the development of MHCPs and planning their evaluation, the PRIME ToC does provide a

simplistic framework of a complex health intervention. PRIME is likely to possess the characteristics of complex systems such as recursive causality, tipping points and emergent outcomes, which have not been expressed explicitly in the PRIME ToC (Shiell, Hawe et al. 2008). We have taken this into account in the analysis of context, as mentioned in the ToC. However, the cross-country ToC still focuses on health services and may inadvertently miss causal pathways leading to unintended consequences of the intervention, for example, the effects of socioeconomic changes on individuals which are not captured by the PRIME evaluation (Shiell, Hawe et al. 2008).

Areas for further research include refining the methods for using ToC to design and evaluate mental health programmes, adaptation of the ToC method for the scale up of mental health services, and testing the use of ToC as a framework for combining process and outcome evaluations (De Silva, Breuer et al. 2014).

In conclusion, using ToC can assist in planning mental health services. In a multi-country programme evaluating the integration of mental health into primary healthcare (PRIME) we developed a cross-country ToC and district specific ToCs with diverse stakeholders. The district specific ToCs formed the basis of MHCPs in each district and the cross country ToC provided a framework to identify indicators for key outcomes along the causal pathway of the MHCPs. This in turn informed the development of the PRIME evaluation design. The cross-country ToC may be a useful heuristic device which can be used and adapted by other programmes when planning the integration of mental health into primary care in low resource settings.

4.6 Declarations

4.6.1 Funding

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Chapter 5. Unravelling the effect of mental healthcare plan inputs on service utilisation in primary care in Nepal: combining Theory of Change and qualitative comparative analysis approaches

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5.1 Abstract

5.1.1 Background

The integration of mental health services into primary care is essential to improve the coverage of mental health services in low resource settings. Multiple and complex interventions to provide mental health services of at district, facility and community levels are necessary. The evaluation of these intervention packages is challenging, particularly when using routine health services data. This paper aims to determine what combination(s) of conditions identified by the PRIME ToC at facility and community level influenced the mental health service utilisation in the PRIME implementation facilities in Chitwan. In addition, we show how Qualitative Comparative Analysis (QCA) can be used to provide an integrated analysis of data from a ToC.

5.1.2 Methods

We use data from the implementation of a complex multilevel mental health intervention in 10 health facilities in Chitwan, Nepal. We collected data from all facilities at baseline (October to December 2013) and quarterly following the implementation of the interventions (March 2014 to November 2016). The data were analysed using pooled Qualitative Comparative Analysis in fsQCA 2.5.

5.1.3 Results

The following inputs were necessary for high mental health service utilisation: presence of basic and advanced psychosocial care, evidence based identification and treatment

guidelines (WHO mhGAP), referral to tertiary services and the presence of trained Female Community Health Workers. Two additional combinations of inputs were also identified for a high mental health service utilisation: high medication supply, trained facility staff and either the use of a community informant detection tool or a larger proportion of the community had attended community awareness activities.

5.1.4 Conclusions

This study demonstrates that multiple interventions are required to integrate mental health into primary care in low resource settings. These include supply side factors such as formalised approaches to health worker detection and treatment, training of health workers, supervision, and demand side factors such as increasing awareness in the community and community case finding. ToC can be used to provide an integrated analysis of data from a ToC therefore helping to shed light on the black box of complex multi-level interventions.

5.2 Background

There is increasing momentum for the integration of mental health services into primary healthcare to address the mental health treatment gap, which is especially marked in low and middle income countries (Saxena, Funk et al. 2013). Barriers to integration such as including low investment in mental health, staff resistance to decentralisation, few people trained in mental health care and overburdened primary healthcare staff with minimal supervision remain (Saraceno, Van Ommeren et al. 2007).

Integration of mental health services into primary healthcare requires multiple intervention components, including case finding, assessment, and psychosocial and pharmacological treatment (Thornicroft and Tansella 2013, Thornicroft and Tansella 2013). The role of mental health specialists shifts toward providing supervision for primary care staff, consultation for complex cases, and assessment and treatment of cases that cannot be managed at primary care level (Thornicroft and Tansella 2013). Despite the evidence for the each of the above components of care in the literature (Benegal, Chand et al. 2009, de Jesus Mari, Razzouk et al. 2009, Patel, Simon et al. 2009, Patel and Thornicroft 2009) and the development of evidence based guidelines in the form of mhGAP to support this integration by the World Health Organisation (WHO) (Dua, Barbui et al. 2011) , there is little guidance for the implementation and effectiveness of these intervention components implemented into routine care in low resource settings (Patel and Thornicroft 2009, Dua, Barbui et al. 2011). Developing such guidance is difficult because evaluation of the implementation of multiple complex health interventions into routine health services is challenging, particularly

when the implementation relies on health system resources such as staff, medication and space (Shidhaye 2015) and is constrained by what is feasible within the health system (Craig, Dieppe et al. 2008)

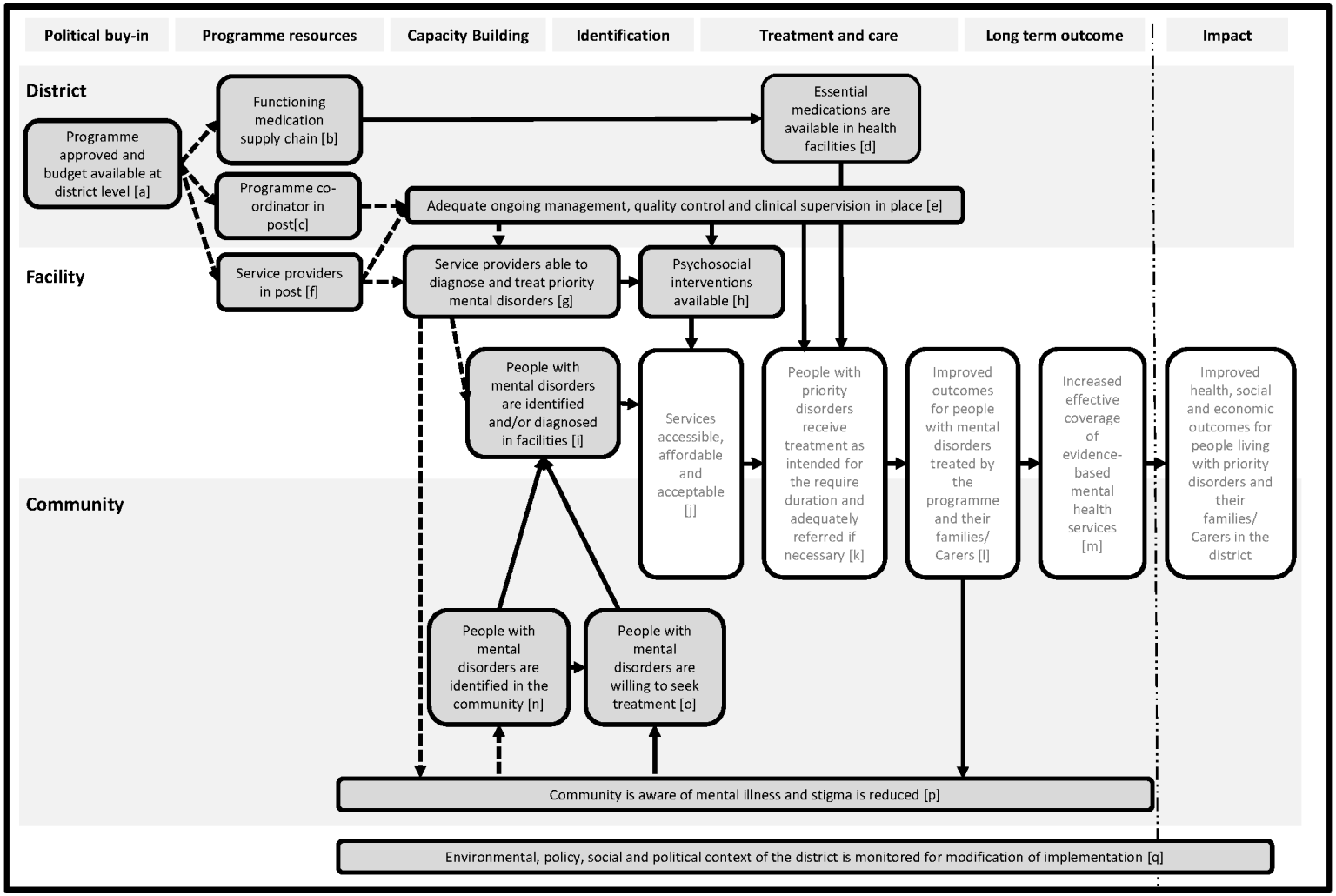
The mental healthcare situation in Nepal exemplifies many of the global challenges to the integration of mental healthcare. As part of a multi-year mental health services implementation research project, the Programme for Improving Mental Healthcare (PRIME) (Lund, Tomlinson et al. 2012), Jordans and colleagues (Jordans, Luitel et al. 2016) developed and implemented a district mental healthcare plan (MHCP) in Chitwan, Nepal which focused on the detection and treatment of depression, alcohol use disorders, epilepsy and psychosis. It was developed through comprehensive formative work (Jordans, Luitel et al. 2013), including the development of a Theory of Change (ToC), and pilot testing in two health facilities (Jordans, Luitel et al. 2016) and is described in detail below. Although most of the intervention components were evidence-based, it is not clear which components of the MHCP are essential in what combination for an increase in mental health service utilisation at facility level in Nepal.

5.2.1 Conceptual Framework for the evaluation

We developed a Theory of Change (ToC) to assist with both the development and evaluation of MHCPs (Breuer, De Silva et al. 2016, Breuer, De Silva et al. 2016, De Silva, Rathod et al. 2016) in the five PRIME countries, including Nepal (Jordans, Luitel et al. 2016). ToC is a theory-driven planning and evaluation approach that identifies the short-, medium- and long-term outcomes of the intervention in order to unpack the "black box" of complex interventions (De Silva, Breuer et al. 2014). We use the Medical Research Council Guidance definition of complex interventions: interventions which contain multiple interventions,

causal strands, outcomes, groups and organisational levels (Craig, Dieppe et al. 2008). The PRIME ToC outlined the programme theory for how the intervention would lead to improved health, social and economic outcomes for people living with priority disorders and their families and carers in the district (Breuer, De Silva et al. 2014, Breuer, De Silva et al. 2016). The PRIME ToC outlines the outcomes required to achieve this impact in relation to political buy-in, capacity building, identification of mental illness and treatment and care at district-, facility- and community-level (Figure 1, Appendix 4.1). Mapped onto these were the intervention components required to achieve these short- and medium-term outcomes, as well as indicators to measure progress. This process and the resultant ToC is described in detail elsewhere (Breuer, De Silva et al. 2014, Breuer, De Silva et al. 2016). A summary ToC is shown in Figure 5.1 with the detailed ToC included in Appendix 4.1.

Although the ToC provided us with a framework to develop the PRIME MHCPs, results from a recent systematic review found no papers that evaluated process and outcomes simultaneously (Breuer, Lee et al. 2016). Qualitative comparative analysis (QCA), a case-oriented method developed in the social sciences for analysis of data in comparative case studies, holds promise as a way to do this (Kane, Lewis et al. 2014).



The subsection of the ToC used in this analysis is indicated with grey blocks.

Figure 5-1 PRIME Summary ToC adapted from Breuer et al. (2014)

In summary, it is important to understand which mental health intervention components result in more people accessing services leading to improved health, social and economic outcomes. However, evaluating complex mental health interventions integrated into routine settings is difficult, particularly when using routine data. The PRIME ToC provides a conceptual framework for the evaluation of these interventions although there is little guidance on how the process and outcomes data from ToC can be combined in one analysis. This paper aims to determine what combination(s) of conditions identified by the PRIME ToC at facility and community level influenced the mental health service utilisation in the PRIME implementation facilities in Chitwan. In addition, we show how QCA can be used to provide an integrated analysis of data from a ToC.

5.3 Methods

We conducted a longitudinal case study based based on the PRIME ToC indicators (Breuer, De Silva et al. 2016, De Silva, Rathod et al. 2016), including the collection of routine service utilisation data.

5.3.1 Setting and intervention

Nepal has a recent history of insurgency followed by a delay in the drafting of the constitution (Luitel, Jordans et al. 2015). Although Nepal's mental health policy was drafted in 1997 and includes the provision of mental health services in primary health care, it has not been implemented (Upadhaya, Jordans et al. 2017).

This study was set in Chitwan (population 579,984) (Central Bureau of Statistics 2014), the implementation area for the Programme for Improving Mental Healthcare in southern Nepal. The MHCP was implemented in 10 health facilities and their surrounding areas. Nine of these were health posts which provides outpatient services and one was a primary health care centre, which also provides emergency services. Female community health volunteers (FCHVs) who are trained in basic health promotion and referral are based in the community surrounding the health facilities.

Prior to the implementation of PRIME in Chitwan, here had been ad hoc mental health training by NGOs and tertiary centres for primary health care staff. Lack of supervision and refresher training meant that in practice there was no consistent mental health service provided in primary care (Luitel, Jordans et al. 2015). In addition, there was a limited and erratic supply of psychotropic medications (phenobarbitone and amitriptyline only), no

counselling or psychotherapeutic services available and no standardised guidelines or treatment protocols (Luitel, Jordans et al. 2015).

The PRIME MHCP was implemented at the district, facility and community levels (Jordans, Luitel et al. 2016) . At the district level, engagement and advocacy activities were conducted with health service managers, and ensuring there was a functioning referral system for complex or treatment-resistant cases to specialist mental health services. At the health facility level, the plan included service provider awareness, screening and assessment following the WHO mhGAP intervention guide (World Health Organization 2010), brief psychosocial support derived from structured interventions adapted from the Healthy Activity Programme (HAP) (Chowdhary, Anand et al. 2015) and Counselling for Alcohol Problems (CAP) (Dabholkar, Nadkarni et al. 2014) , pharmacological management and follow up for monitoring and treatment adherence. At the community level, the MHCP included community awareness programmes conducted by PRIME community counsellors in coordination with the Female Community Health Volunteers (FCHVs), pro-active case detection in the community using Community Informant Detection Tool (CIDT) (Jordans, Kohrt et al. 2015), as well as the provision of the HAP and CAP by a community counsellor. The CIDT is a novel vignette-based case finding tool, which was developed for use in Nepal (Jordans, Kohrt et al. 2015, Jordans, Kohrt et al. 2017).

5.3.2 Sample and measures

All of the 10 health facilities in Chitwan where the PRIME MHCPs were implemented at each time point were selected as cases. The health facilities are described in Table 5.1.

Table 5-1 PRIME MHCP Implementation Facilities in Chitwan, Nepal

Facility	Facility type	*Catchment area*		Rural vs Urban
		Size (km^2)	Population	
1	Health post	3	13929	Semi-rural
2	Health post	5	11195	Rural
3	Health post	5	3862	Semi-rural
4	Health post	3	19066	Rural
5	Health post	4	6506	Semi-rural
6	Health post	3	11500	Rural
7	Health post	10	11508	Rural
8	Primary healthcare centre	6	7674	Semi-rural
9	Health post	13	8057	Rural
10	Health post	7	15071	Rural

The majority of the data used in this study were collected through a quarterly profile of the implementation facilities designed to collect facility level indicators outlined in the PRIME Theory of Change (De Silva, Rathod et al. 2016) and Table 5. 2. These data were collected at baseline and quarterly until November 2016. Data collected included monthly health information system data on mental health patients (which were averaged over the quarter) and quarterly data on trained staff, supervision, medication supply and presence of PRIME intervention components. Data at the community level were collected by the programme implementers.

5.3.3 Qualitative Comparative analysis

We analysed the data using QCA, a case-oriented method developed in the social sciences for analysis of data in comparative case studies (Ragin 1999). QCA can be used to analyse both quantitative and qualitative data from multiple sources by using set-theory and Boolean algebra to identify patterns in data (Garson 2016). Rather than identify single

conditions or variables which lead to an *outcome*, QCA seeks to identify causal pathways or configurations of causes in diverse contexts (Warren, Wistow et al. 2014). The relative importance conditions can be determined by 1) whether they are identified as necessary conditions with higher consistency scores indicating a stronger relationship with the outcome; and 2) conditions that are included in more than one causal pathway of sufficient causes.

QCA is particularly suited for small numbers of cases where statistical analysis is not possible. Inherent in QCA is equifinality, i.e. that there can be multiple causal factors within a pathway or across distinct pathways to an outcome (Warren, Wistow et al. 2014). This recognises causal complexity (McAlearney, Walker et al. 2016), unlike many statistical methods which isolate the effects of one factor on the outcome by controlling for all other factors.

QCA is asymmetrical. This means that the causal pathways shown to lead to a lack of outcome are not merely the inverse of those leading to the outcome but could be completely different causal pathways. For more detail on the QCA approach, we refer to Kane et al. (2014).

QCA Outcomes and Condition Sets

We used the PRIME Summary ToC (Figure 1) as our conceptual framework to determine the hypothesised facility and community level pathways which led to increased service utilisation, i.e. the ToC outcome: "*People with mental disorders are identified and/or diagnosed in the facility*".

We used the section of the ToC leading up to the service utilisation to identify the *condition sets*, which are the conditions of interest which may or may not result in the outcome. These are listed in the second and third column of Table 5.2. We included all indicators for the short- and medium-term outcomes in the sub- section of the PRIME ToC as condition sets except for three: 1) programme approved and budget available at district level; 2) programme co-ordinator in post, and 3) people with mental disorders are willing to seek treatment. The first two were excluded because the data were collected at district level and did not vary across facilities and therefore could not be included in the QCA. Therefore we have limited this analysis to understanding the community and facility level pathways outlined in the ToC (as indicated in the grey boxes in Figure 1). The third was excluded because these data were collected qualitatively and the sample size at each of the facilities was not large enough to be disaggregated by facility.

We added two additional condition sets not in the ToC: 1) availability of mhGAP protocols for detection and treatment of mental illness and 2) referral to tertiary care. The first was added to mirror the existing indicator, availability of psychosocial interventions, and the second had been included further along the ToC. However, the availability of referral mechanisms could also contribute to willingness of healthcare workers to identify people with mental illness. Therefore, we included it as a condition set in this analysis.

Data collection

A baseline profile was conducted to collect data from October to December 2013. Following implementation of the district mental healthcare plans (beginning in March 2014), the data was collected quarterly until November 2016. Where multiple indicators were used for one condition set, they were aggregated to represent one condition. For example, we averaged

medication supply for all medications outlined in the MHCP to create a summary condition set for medication supply. Where we were unsure whether to combine the indicators from a conceptual point of view, we conducted a factor analysis to ensure they loaded on the same factor.

In order to minimise the number of condition sets, multiple indicators for one condition were aggregated. For example, supervision for pharmacological and psychological management at facility level were combined into 1 condition set. The ToC indicators and the process used to combine indicators are outlined in Table 5.2, column 3.

Once the outcome and condition sets were finalised, each case was calibrated by assigning a value between 0 and 1 under each condition set to describe set membership or the degree to which the case meets that condition. Zero is fully out of the set, 1 fully in the set and 0.5 neither in nor out of the set.

The data for the outcome and each condition set were calibrated in various ways, using a theoretical understanding of the indicators and calibration commands in the fuzzy package in STATA (Longest and Vaisey 2008, Statcorp 2013). To aid the interpretation of the results, we ensured that the data were calibrated carefully to ensure meaningful interpretation for programmatic and policy outcomes. The outcome, for example, was calibrated as follows: Monthly mental health patients as a proportion of all monthly facility patients was averaged over each quarter. The range across the implementation period was 0 – 10.69 % with a median of 1.79%. These proportions were graphed over time to determine the pattern at baseline, immediately following implementation, and over the remaining period of implementation. In most facilities, the percentage of patients attending for mental illness increased to above 2% during the implementation, with 25% reaching 3% and above. We

therefore decided that 0% was fully out of the set, 1% neither in nor out of the set and 3% fully in the set. We used a direct transformation in STATA to calibrate levels of deviation from these anchors in terms of log odds and to obtain the fuzzy values (Ragin 2008). The calibration approaches for the conditions are outlined in Table 5.2. The calibrated data can be found in Appendix 5.1.

Table 5-2 Outcome and condition sets, indicators and calibration for QCA

ToC Outcomes	Condition	Indicators	Data collection	Calibration
Long term outcome	Primary care service utilisation for mental illness	Monthly mental health patients as a percentage of monthly clinic patients averaged over the quarter.	Facility profile	Monthly mental health patients as a percentage of monthly clinic patients was averaged over the quarter. Calibrated in STATA using a "direct" transformation to calibrate levels of deviation from anchors, in terms of log odds. Anchors: 0 (fully out of the set), 1 (mid-point) and 3 (fully in the set).
Short and medium term outcomes	Medication supply	Essential medications were available at the facility in the last month	Facility profile	Coded the availability of all medications outlined in the MHCP: all of the time (1), most of the time (0.75), sometimes (0.5), rarely (0.25) and not available (0). An average score was obtained for all medication.
	Supervision (facility)	All facility staff receive supervision on a regular basis as defined by the MHCP and guidelines	Facility profile	Number of monthly supervision visits provided at facility level was calculated as a proportion of the number recommended in the mental healthcare plan. This was averaged over the quarter for each type of supervision. The data was naturally calibrated into 0 (fully out of the set), 0.333 (one supervision session every 3 months, more out than in the set). 0.666 (two supervision session every 3 months, more in that out of the set), 1 (fully in the set). Following factor analysis the data was averaged to create a mean facility supervision score.
	Supervision (community)	All community staff receive supervision on a regular basis	Facility profile	Number of monthly supervision visits provided at community level was calculated as a proportion of the number recommended in the mental healthcare plan. This

	as defined by the MHCP and guidelines		was averaged over the quarter for each type of supervision. The data was naturally calibrated into 0 (fully out of the set), 0.333 (one supervision session every 3 months, more out than in the set). 0.666 (two supervision session every 3 months, more in that out of the set), 1 (fully in the set). Following factor analysis the data were averaged to create a mean community supervision score.
Trained human resources (facility)	Adequate numbers of trained human resources as per the MHCP are available at facility level	Facility profile; process data	Number of trained staff was calculated as a proportion of the government recommended staff numbers for the cadre of worker. This was initially done for prescribers and non-prescribers but averaged following a factor analysis. Calibrated in STATA using a "direct" transformation to calibrate levels of deviation from anchors, in terms of log odds. Anchors: 0 (fully out of the set), 0.6 (mid-point) and 1 (fully in the set).
Trained human resources (community)	Adequate numbers of trained human resources as per the MHCP are available at community level.	Facility profile	Number of trained FCHVs was calculated as a proportion of the government recommended staff numbers for the cadre of worker. We did not disaggregate between FCHVs trained in detection and referral and those with additional training in home based care.
Facility psychosocial interventions	Facility psychosocial interventions available	Facility profile	Average of binary variables indicating the availability (1) or absence (0) of basic and advanced psychosocial interventions for all four mental illnesses outlined in the mental healthcare plan.
mhGAP	mhGAP available	Facility profile	Average of binary variables for availability of mhGAP for all four mental illnesses outlined in the mental healthcare plan.
Referral to tertiary care	Referral to tertiary services available	Facility profile	Binary variable on availability of referral services in the last month

	Community identification	Increased number of cases detected and referred by community health workers	Facility profile	Average number of community identification detection tool referral forms received at the facility per quarter. Calibrated in STATA by ranking the variables and then standardising them between 0 and 1. Resultant fuzzy value is more out than in the set if there is less than 1 CIDT per month.
	Community awareness and stigma reduction	Proportion of people reached by community awareness programmes	Facility profile	The cumulative proportion of people who had attended community sensitization sessions was calculated using the cumulative number of people attending the sessions over the population of the VDC. The indicator was calibrated in STATA using a “direct” transformation to calibrate levels of deviation from anchors in terms of log odds. Anchors: 0 (fully out of the set), 0.01 (mid-point) and 0.04 (fully in the set).

Data analysis

The data were analysed using pooled QCA (Hino 2009) in fsQCA 2.5 (Ragin and Davey 2014). where data are pooled for all facilities and outcomes and which therefore treats each observation for each facility and each time point as an independent observation.

We conducted each of the following analysis steps for the outcomes 'high' and 'low mental health service utilisation' as QCA is asymmetrical. We first identified necessary conditions from the list of conditions outlined in Table 2 using the Necessary Conditions option in fsQCA and XY plots. Necessary conditions are conditions for which the outcome is almost always a result of a causal condition (Kane, Lewis et al. 2014). As outlined by Garson, we defined conditions as necessary when the consistency, or degree to which the outcome was a result of the condition, was greater than 0.90 (Garson 2016).

Secondly, we constructed a truth table with the remaining conditions to determine sufficient causal pathways. A truth table is an intermediate step in the QCA analysis that shows all possible configurations of conditions, and the number of cases that exhibit each causal configuration, together with a consistency score for the causal configuration. The abbreviated truth tables containing only the causal configurations for which data was available for the outcomes of high and low mental health service utilisation are presented in Tables 5.3 and 5.4. We applied a frequency threshold of 2 and used a standard consistency threshold of 0.8 (Garson 2016) and the standard analysis option in fsQCA.

Table 5-3 Abbreviated truth table for high primary care service utilisation for mental illness.

Condition sets						Number of cases	Outcome	Raw consistency
Medication	**Facility Training**	**Facility supervision**	**Community supervision**	**Use of CIDT**	**Community awareness**			
1	1	0	0	1	1	6	1	0.99
1	1	1	0	1	1	6	1	0.97
1	1	1	0	0	1	4	1	0.97
1	1	0	0	0	1	14	1	0.93
1	1	1	1	0	1	10	1	0.91
1	1	1	1	1	1	13	1	0.89
1	1	0	0	1	0	4	1	0.83
1	0	0	0	0	0	2	0	0.72
0	1	0	0	0	0	7	0	0.47
0	0	0	0	0	0	12	0	0.30

Note: Only the rows where data was available have been included and not the logical remainders

Table 5-4 Abbreviated truth table low primary care service utilisation for mental illness

Condition sets												
Medication	**Trained Facility Staff**	**Trained Community staff**	**Psychosocial interventions**	**MHGAP**	**Referral**	**Facility supervision**	**Community supervision**	**Use of CIDT**	**Community awareness**	**Number of cases**	**No outcome**	**Raw consistency**
0	1	0	1	0	1	0	0	0	0	4	1	1.00
0	0	0	1	0	1	0	0	0	0	3	1	1.00
0	1	0	0	0	1	0	0	0	0	2	1	1.00
0	0	0	0	0	0	0	0	0	0	4	1	0.99
1	1	1	1	0	1	0	0	1	0	3	1	0.96
0	0	0	0	0	1	0	0	0	0	5	1	0.84
1	1	1	1	1	1	1	1	0	1	10	0	0.47
1	1	1	1	1	1	1	1	1	1	13	0	0.44
1	1	1	1	1	1	1	0	0	1	4	0	0.40
1	1	1	1	1	1	1	0	1	1	6	0	0.39
1	1	1	1	1	1	0	0	1	1	5	0	0.38
1	1	1	1	1	1	0	0	0	1	14	0	0.34

Note: Only the rows where data was available have been included and not the logical remainders

fsQCA uses Boolean miniminisation to simplify the combinations of conditions and provide sufficient combinations of conditions associated with the outcome. fsQCA provides three types of solution according to the simplifying assumptions used: (1) a complex solution, which minimises the solution based on the available data only, (2) an intermediate solution, which uses theoretical knowledge to determine which logical remainders to include and (3) a parsimonious solution which finds the simplest solution without evaluating the plausibility (Rihoux and Ragin 2008). For the intermediate solution, logical remainders were coded according to the programme theory outlined in the ToC. Logical remainders are the causal configurations in the truth table for which there was no available data.

We calculated solution consistency and coverage based on the findings. Coverage refers to the degree to which the causal condition explains the outcome in the sample (Kane, Lewis et al. 2014). There is no specific cut-off for coverage because a lower coverage may indicate a more uncommon causal pathway. We present both the intermediate and complex solutions of sufficient conditions from the truth table analysis in the table and only the intermediate solutions in the narrative.

This study was approved by Faculty of Health Sciences Human Research Ethics Committee, University of Cape Town (HREC 412/2011 and 247/2013) and the Nepal Health Research Council (NHRC 10/2013) and conformed to the principles embodied in the Declaration of Helsinki. Permission to collect data was obtained from the managers of all 10 facilities to obtain facility level data.

5.4 Results

The results of the QCA for high and low mental health service utilisation at primary care facilities are outlined in Table 5-5 and 5.6 respectively.

In summary, the presence of basic and advanced psychosocial care (consistency 0.97, coverage 0.70), mhGAP (consistency 0.92, coverage: 0.77), referral to tertiary services (consistency 1.00, coverage 0.63) and trained FCHVs (consistency 0.97, coverage 0.74) were necessary but not sufficient for the outcome of a high mental health service utilisation.

In addition, two causal pathways were identified as sufficient for a high mental health service utilisation in the intermediate solution of the truth table analysis. Mental health service utilisation was high in facilities at times when medication supply was high, facility staff were trained and either the CIDT was used frequently or a larger proportion of the community had attended community awareness activities. The solution consistency was high at 0.85 and with a moderate coverage of 0.74. This indicates that these combinations of conditions lead to the outcome in a high proportion of cases and that a moderate proportion of the cases with the outcome are a result of this combination of conditions.

There were no necessary conditions for low mental health service utilisation at primary care facilities and one causal pathway was identified as sufficient in the intermediate solution in the truth table analysis. Mental health case load was low in facilities at times when there was lack of facility and community supervision, lack of mhGAP services and a low proportion of the community members attending community awareness activities. The consistency was high for this solution (0.90), but the coverage moderate (0.56). This indicates that these

combinations of conditions lead to the outcome in a high proportion of cases, but that only a moderate proportion of the cases with low service utilisation is a result of this combination of conditions.

Table 5-5 Necessary and sufficient causes for high mental health service utilisation

Conditions		Necessary causes				Sufficient causes				
						Complex solution			Intermediate solution	
						1	2	3	1	2
Medication						+	+	+	+	+
Trained staff	Facility					+	+	+	+	+
	Community	+								
Supervision	Facility						+	—		
	Community					—				
Community level activities	CIDT use							+	+	
	Community awareness					+	+	—		+
Services available	Psychosocial care		+							
	mhGAP			+						
	Referral				+					
Condition	**Consistency**	**0.97**	**0.97**	**0.92**	**1**	**0.94**	**0.89**	**0.89**	**0.85**	**0.88**
	Coverage	**0.74**	**0.70**	**0.77**	**0.63**	**0.44**	**0.49**	**0.21**	**0.46**	**0.68**
Solution	**Consistency**	**1.00**				**0.87**			**0.84**	
	Coverage	**0.63**				**0.68**			**0.74**	

+ indicates presence of condition in causal pathway and — indicates absence of the condition. Each column under sufficient causes is one causal pathway. Each condition in the

causal pathway should be combined with a logical AND. For example: Medication AND Trained Facility Staff AND Absence of community supervision AND community awareness

Table 5-6 Necessary and sufficient causes for low mental health service utilisation

Conditions		**Sufficient causes**			
		Complex solution			**Intermediate solution**
		1	**2**	**3**	**1**
Medication		—	—	**+**	
Trained staff	Facility		—	**+**	
	Community	—	—		
Supervision	Facility	—	—	—	—
	Community	—	—	—	—
Community level activities	Community informant detection tool use	—	—	**+**	
	Community awarennes	—	—	—	—
Services available	Psychosocial care available		—	**+**	
	mhGAP available	—	—	—	—
	Referral to tertiary services	**+**		**+**	
Condition	**Consistency**	**0.91**	**0.90**	**0.96**	**0.90**
	Coverage	**0.32**	**0.21**	**0.08**	**0.56**
Solution	**Consistency**	**0.94**			**0.90**
	Coverage	**0.49**			**0.56**

+ indicates presence of condition in causal pathway and — indicates absence of the condition

5.5 Discussion

This study shows that in Nepal, a combination of formal mental health service intervention components, training, medication and community intervention components lead to increased mental health service utilisation in primary care facilities. In contrast, at times when mhGAP availability, supervision and community awareness activities were low, mental health service utilisation was also low. This indicates that different inputs or intervention components may be important to the establishment and sustainability of mental health services in the community.

The identification of three defined treatment packages in the facilities were necessary conditions for an increase in service utilisation is in line with the existing evidence on core packages of care (Patel and Thornicroft 2009, Thornicroft and Tansella 2013, Thornicroft and Tansella 2013). These services were defined as follows: mhGAP services were available when all the required inputs were in place. Specifically, the appropriate staff were trained, medication, mental health outpatient register, protocols, mhGAP flowchart and brochures were available. Similarly, basic and advanced psychosocial services were defined as available when the appropriate staff were trained and the mental health outpatient register, basic psychosocial manual, HAP/CAP manual, brochures and flowchart were available. Our results show that formal guidelines and reporting and referral need to be in place for an increase in detection and treatment by primary healthcare workers. This can be seen in the

increase in service utilisation, which occurred following the formalisation of these services in the clinic rather than when training alone was conducted. The results of the truth table analysis also indicated that training needed to be combined with medication and either community awareness activities or case finding in the community. This may give some insight into why the evidence for the effectiveness of training alone on detection of mental illness is mixed, particularly in the long term (Painuly and Sharan 2008, Goncalves, Fortes et al. 2013, Jenkins, Othieno et al. 2013, Kauye, Jenkins et al. 2014).

This study highlights the importance of creating demand at community level. Trained FCHVs were a necessary condition of high mental health service utilisation. In the MHCP, FCHVs are responsible for a large proportion of demand creation activities, namely administering the community detection tool (CIDT) and organising community awareness programmes which are conducted by the community counsellors (Jordans, Luitel et al. 2016). FCHVs also provide home based care services for patients who have stopped attending the facility. This includes psychoeducation, emotional support and motivation to seek services at the health facility. For high mental health service utilisation, the two sufficient causal pathways included both facility-level conditions (training and medication provision) and either high use of the CIDT or a higher proportion of the community reached with community awareness programmes. The findings in this study of the importance of demand-side factors corroborate the findings of a qualitative study in Chitwan exploring demand and access conducted in the intervention development phase of PRIME (Brenman, Luitel et al. 2014). Brenman and colleagues (Brenman, Luitel et al. 2014) used framework analysis of qualitative interviews and focus group discussions with stakeholders with the PRIME ToC as their

conceptual framework. They found that many of the barriers to demand and access to mental health services were at the community-level, including high levels of stigma around mental health, low mental health awareness and lack of awareness about treatment availability. They also suggested that in addition to service provision at the facility level, working at the community level to increase awareness of mental illness and working with local understandings of mental illness was essential to ensure uptake of services. A community based survey of barriers to care in Chitwan showed that stigmatising beliefs in the community were a barrier to seeking care (Luitel, Jordans et al. 2017).

We found that supervision was important in ensuring that detection and treatment for mental illness occurs in primary care. Low mental health service utilisation occurred at facilities and times when supervision at facility- and community-level was low, mhGAP was unavailable and low numbers of people in the community were reached by community awareness programmes. The majority of data contributing to this causal pathway is from the initial roll-out of the MHCP when training had been conducted but supervision, mhGAP and community awareness programmes had not reached a substantial amount of people. Understanding the role of lack of supervision and low community awareness and lack of formal mhGAP services is important because integration of mental health care into primary care often consists of short training courses and very little supervision at the district level. This is due to many factors, including the lack of trained mental health specialists to offer supervision and the lack of evidence for the type and quality of supervision required (Kakuma, Minas et al. 2011). However, this study shows that supervision at both the community- and facility-level together may be important to avoid low service utilisation. Structured and ongoing supervision should therefore be seen as a key component of a successful mental healthcare plan together with facility and community level components.

Most previous research on developing packages of care for mental disorders are based on reviewing the existing evidence from systematic reviews, randomised controlled trials and expert opinion and making with recommendations (Patel and Thornicroft 2009, Thornicroft and Tansella 2013, Thornicroft and Tansella 2013). Because this approach prioritises randomised controlled trials, most of the recommendations will have been made from RCTs which test one intervention component, for example, psychological therapies or training. In contrast, this study shows how these MHCP intervention components work together to result in increased service utilisation.

The main contribution of this study is to provide evidence to support a part of the PRIME ToC, which identified specific short- and medium-term outcomes that work together at facility- and community-level to improve identification of people with mental illness in facilities in southern Nepal. In this analysis, we showed that all short- and medium-term outcomes included from the PRIME ToC were either necessary or sufficient (in combination with other conditions) in cases high mental health service utilisation or absent in cases of low service utilisation. This study did not identify specific gaps in the ToC, although the lower coverage of the intermediate solution for the lack of outcome could indicate that there are other causal pathways that have not been identified in this analysis. These could include, for example, the level of facility manager buy-in to the provision of mental health services, quality of facility management, quality of supervision, competing priorities within the health service or contextual factors.

This study makes a methodological contribution as an example of how QCA can be used together with a ToC to analyse routine service implementation data. There have been some recent applications of QCA to health services research (Dill, Chuang et al. 2014, Warren,

Wistow et al. 2014, Goicolea, Vives-Cases et al. 2015, McAlearney, Walker et al. 2016). However, to our knowledge, there have been no studies which have used QCA and ToC or QCA for longitudinal data analysis in health services research. ToC provides a transparent approach to develop a contextually relevant conceptual framework and indicators which can be used to quantify the QCA condition sets and outcomes. QCA can then be used to evaluate where and how the different factors identified by the ToC affect the outcome. QCA is particularly suitable for the analysis of routine implementation data because it seeks to understand causal complexity rather than identify individual risk factors (Kane, Lewis et al. 2014, Kane, Luitel et al. 2017) , uses a relatively small number of cases (in this case health facilities) and can combine data from different sources, including qualitative data. We propose that the combination of ToC and QCA could be expanded beyond health services data to combine process and outcome evaluations for randomised controlled trials. For example, where mixed method data were available for trial participants, a QCA analysis could be used to understand how fidelity, dose, participant characteristics, therapist characteristics and other contextual factors are related to the outcome.

During the process of applying QCA together with QCA, we learned several lessons. Firstly, using a conceptual framework, such as ToC, to guide QCA is important to identify the outcome and condition sets as well as providing a theoretical basis for how to treat logical remainders. Secondly, the number of conditions needs to be kept to around 5-7 to avoid the "limited diversity problem" (Kane, Lewis et al. 2014) which occurs when there are too many conditions in relation to the number of cases which prevent Boolean Minimisation of the truth tables and result in causal pathways with many conditions and low coverage. This is similar to the problem in frequentist statistics of including too many explanatory variables in a multivariate linear regression without an adequate sample size. To avoid this problem, we

aggregated similar indicators prior to data analysis, for example, proportion of trained prescribers and non-prescribers and the number of trained home-based care workers and FCHVs. Other approaches to avoid limited diversity include 1) a comprehensive approach where all conditions are included iteratively in the analysis until the most parsimonious solution is reached; or 2) a two-step approach where an analysis of the distal conditions is conducted first, followed by the proximal conditions (Yamasaki and Rihoux 2009). Thirdly, data calibration is one of the key steps in QCA and should be conducted with a theoretical understanding of the values chosen, i.e. that 1 is fully in the set, 0 is fully out of the set and that 0.5 neither in nor out of the set. The calibration of data should be conducted using thresholds that are meaningful to the programme. Although tools exist in STATA and other software to calibrate continuous variables, the distribution of the resulting calibrated data should be checked to ensure that the interpretation of the data is in line with the theoretical understanding. Because of the iterative nature of QCA, it is possible and may be necessary to recalibrate the data following the analysis.

This study has some limitations. Because the district level effects were the same across the district, we could only assess the facility- and community-level part of the ToC and could not assess the effect of the engagement, service strengthening and input into the medication procurement system, which was identified in the ToC. This will be expanded upon in another paper which investigates the district level implementation of the Nepal MHCP. In addition, although the PRIME MHCP was implemented in routine health services, a significant amount of support was provided by TPO Nepal, the NGO implementing the study. For example, they provided medication when the government had not yet started supplying this and they provided staff to assist with supervision, and directly implemented the community counselling component. As a result, most of the components of the MHCP were

relatively well implemented in most of the facilities. However, as most inputs were available at similar times it is difficult to determine which ones actually had an effect. Although the MHCP was piloted in two districts and there was regular supervision to ensure that interventions were delivered as intended, there were no formal fidelity assessments conducted prior to this study. This analysis also does not take into account some of the weaknesses of using longitudinal data, such as autocorrelation, non-stationarity and seasonality (Lagarde 2012). It may be worth exploring how to combine statistical approaches for longitudinal data analysis with QCA, for example, by using time differencing QCA to look at the change in conditions over the time period of interest and using segmented linear regression to determine the presence or absence of the outcome. Another limitation is the use of pooled QCA which treats each time point as independent and does not take into account the between clinic variation, it may be possible to conduct a fixed effects QCA as software are expanded (Hino 2009). Lastly, QCA and the ToC did not take into account some of the features of complex adaptive systems such as tipping points, feedback loops, emergence or unintended consequences (Glouberman and Zimmerman 2002). Despite this, the approach does explore the multiple facility and community level pathways required to achieve the outcome and therefore goes some of the way towards unpacking the black box of complex health interventions.

5.6 Conclusions

This study has shown that multiple packages of care are required to integrate mental health into primary care in low resource settings. Specifically, that a combination of formal manualised approaches to health worker detection and treatment, both psychological and

pharmacological, referral pathways and trained community workers, were necessary for high mental health service utilisation in Chitwan. In addition, a combination of training, medication and either community awareness or use of community case finding was important. ToC can add value to QCA by identifying the causal pathways and the potential necessary and sufficient conditions which can be explored through QCA. Policy makers who are planning integrated mental healthcare should ensure that mental healthcare plans are carefully constructed with multiple packages of care. These should include supply side factors such as formalised approaches to health worker detection and treatment, training of health and community workers, supervision and medication supply. In addition, demand side factors such as increasing awareness in the community and community case finding should be included.

5.7 Declarations

5.7.1 Ethics approval and consent to participate

Permission was obtained from the managers of all 10 facilities to obtain facility level data. This study was approved by Faculty of Health Sciences Human Research Ethics Committee, University of Cape Town (HREC 412/2011 and 247/2013) and the Nepal Health Research Council (NHRC 10/2013).

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Chapter 6. Theory of Change for complex mental health interventions: 10 lessons from the Programme for Improving Mental Healthcare

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Theory of Change (ToC) has gained prominence in recent years as an alternative way to conceptualise programme design and evaluation in global mental health (De Silva, Breuer et al. 2014, Asher, De Silva et al. 2016, Chibanda, Verhey et al. 2016). This has been fuelled by renewed interest from development funders (Vogel 2012) and the limitations of conventional research designs to evaluate complex global mental health interventions (Mackenzie 2008).

ToC is a theory driven approach for intervention development and evaluation which makes explicit the causal pathways leading to the outcome of a programme. ToC was initially developed by evaluators working in education and development sectors in the 1990s (Connell and Kubisch 1998) and has been used for more than 20 years in public health research (Breuer, Lee et al. 2016), mostly in high income countries. ToC has been used successfully in the United States in interagency planning for youth at risk (Hernandez and Hodges 2006) and in the evaluation of various government initiatives in the United Kingdom (Sullivan, Barnes et al. 2002, Cole 2003).

ToC enables planners and evaluators to make explicit a number of aspects of a programme, including the impact and the short-, medium- and long-term outcomes required to achieve the impact. In addition, the ToC outlines necessary interventions, the assumptions inherent in the programme, and the context (Vogel 2012).

We have proposed that ToC could strengthen all four phases of the MRC guidance for the evaluation of complex interventions in both low and high resource settings (Craig, Dieppe et al. 2008, De Silva, Breuer et al. 2014). Specifically, it will assist in the 1) *development* of the intervention through stakeholder consensus and creating realistic expectations of the

impact of interventions, 2) *feasibility/piloting* stage of the intervention by highlighting knowledge gaps and barriers to implementation, 3) *evaluation of the intervention* by combining process and outcome evaluation in one framework; and 4) *implementation* of the intervention by ensuring the interventions and results are relevant to stakeholder's expectations (De Silva, Breuer et al. 2014).

Since then, we have tested this approach in the Programme for Improving Mental healthcare (PRIME) (Breuer, De Silva et al. 2014, Breuer, De Silva et al. 2016, De Silva, Rathod et al. 2016), a large multi-country study which aims to provide research evidence for the integration of mental healthcare into primary healthcare in Ethiopia, India, Nepal, South Africa and Uganda (Lund, Tomlinson et al. 2012). Here we present 10 lessons we have learnt in PRIME, from developing the ToC through workshops to the evaluation and analysis, which highlight the strengths and limitations of the ToC approach.

1) ToC is useful when interventions are complex.

Complex health interventions contain multiple interacting components, causal strands, feedback loops and emergence of unexpected outcomes (Craig, Dieppe et al. 2008). Interventions can be implemented in multiple locations with different governance structures, increasing the complexity of even simple interventions. ToC focuses on the key, essential outcomes of the programme while allowing flexibility in how this is achieved across different contexts. For example, the complex interventions developed and evaluated by PRIME were district level mental healthcare plans in five countries (Hanlon, Fekadu et al. 2016). We used the ToC map to summarise a complex system of multiple causal pathways across three levels of the health system (Breuer, De Silva et al. 2016). We then mapped

intervention packages onto these causal pathways, for example a detection package at community level, a psychosocial treatment package at facility level or a mental health awareness package at district level. Each of these packages had the same function across countries, but the form differed as they were developed for different countries according to resources, evidence, need, feasibility and acceptability. This allowed comparability across settings but flexibility to ensure the intervention packages were fit for purpose (Hawe, Shiell et al. 2004) .

2) *ToC workshops can help to develop a contextualised mental healthcare plan with stakeholder buy-in*

Implementers, researchers, policy makers and service users each have their own implicit understanding of how and why a complex intervention works and what outcome it will achieve (Peters 2014). Including a variety of stakeholders in ToC workshops allows all stakeholders to co-develop the ToC and make explicit the steps along the causal pathway (Andersen 2004).

The PRIME ToC development process was extensive and included a cross country ToC workshop, 2-4 workshops in each of the five PRIME countries and revision of the cross country ToC (Breuer, De Silva et al. 2014, Breuer, De Silva et al. 2016). This resulted in one ToC map per country and a ToC across all five countries. The ToCs were influenced by each other and built on prior work of the PRIME consortium including a draft framework which outlined the three levels of the health system at which PRIME planned to intervene (Lund, Tomlinson et al. 2012). We found that ToC workshops assisted us in developing a logical ToC map which formed the basis of a contextualised mental health care plan (Breuer, De Silva et

al. 2014). The presence of mental health specialists, researchers, policy makers, district level health planners and management and service providers during the ToC development ensured that the resulting ToCs and mental healthcare plans were relevant, feasible, and that the barriers and facilitating factors supporting this programme were clearly articulated. The presence of stakeholders also ensured their buy-in as they were able to contribute to the conceptualisation of the programme as well as highlight potential problems prior to the development of a detailed implementation plan. Chibanda, Verhey et al. (2016), who used ToC to develop a counselling intervention for common mental disorders in Zimbabwe, found that early engagement helped to build rapport with stakeholders who provided detailed contextual information. This increased the likelihood that the intervention would be successful.

Although ideally the ToC should be owned by all stakeholders, this is often difficult in practice (Sullivan and Stewart 2006). Ownership of the PRIME ToCs most closely resembles elite ownership (Breuer, De Silva et al. 2014). According to (Sullivan and Stewart 2006), this is ownership by small group of leaders (including community leaders) who are responsible for implementing the programme. In PRIME this is due to multiple reasons: 1) the large number of stakeholders involved in the workshops in countries (median 15 (interquartile range 13-22)) making extended consultation difficult; 2) the finalisation of the ToC by PRIME researchers after the workshop; 3) hierarchies within the health service making participation in the workshops uneven (despite our attempts to mitigate this) and 4) the lack of beneficiaries of the programme who attended the ToC workshop (Breuer, De Silva et al. 2014).

3) *ToC workshops are resource intensive*

ToC workshops are resource intensive. These include human resources to plan, facilitate and attend the workshop, and the financial costs of conducting the workshop. To our knowledge, there has been no formal comparison of costs between ToC and other methods to develop and evaluate complex mental health interventions. However, from our experience, there are both higher costs and greater stakeholder input into the development of the ToC compared with other methods of developing a ToC, such as qualitative interviews or document review. Therefore, it is important to determine the level of complexity of the interventions and the extent to which local knowledge and stakeholder buy-in is useful so that a balance between resources and buy-in can be decided on *a priori* by the research team.

4) *ToCs need champions to drive their development and implementation*

ToCs need champions who understand the ToC approach and can drive the ToC development and implementation during the life of the programme (Lee 2014). This includes organising and facilitating the workshops, finalising the resultant ToC map, getting further stakeholder input where required, finalising the evidence base and indicators for the ToC map and ensuring that the evaluation design of the programme measures the indicators outlined in the ToC. In PRIME, we were the ToC champions who led the work across all five countries and were supported by ToC champions in each country who led and facilitated the country workshops and developed the country ToCs.

Despite having champions, there has been no formal revision of the PRIME ToC in any country. There are three likely reasons for this: 1) The data collection for the evaluation of the programme has only recently been completed and analysis is underway; 2) the research teams had competing priorities; and 3) no formal ToC revision of the ToC across and within countries was included in the workplan of the programme. In future projects, we would recommend a formal revision process of the ToC as key points in the process, for example, after piloting and after initial implementation of the programme, and after the final summative evaluation. For example, Asher, Fekadu et al. (2015) used the findings of their pilot study to revise her ToC for a community based rehabilitation intervention for people living with schizophrenia in Ethiopia prior to implementing the intervention in a cluster randomised controlled trial.

5) The approach to ToC development should remain flexible

If the instructions on how to develop, portray or use a ToC become too prescriptive, ToC runs the risk of becoming yet another monitoring and evaluation tool which is used superficially in order to satisfy the requirements of funding agencies. Prinsen and Nijhof describe how logframes were initially developed often with stakeholders using a problem or objective tree. However, now they are largely templates standardised by funding agencies for completion (Prinsen and Nijhof 2015). In PRIME, because we developed these ToCs in addition to our formal monitoring and evaluation requirements from our funder, there was flexibility in how the ToCs were developed which helped to ensure that they represented the causal pathways to change.

6) *ToC can provide a framework for evaluation and assist with identifying indicators for measurement*

Once causal pathways of short-, medium- and long-term outcomes have been developed, indicators are developed for each outcome. This measures the achievement of each step along the causal pathway and distinguishes between implementation failure, where the programme was not implemented as intended, or theory failure, where the programme did not produce the expected outcomes (Patton 2008, De Silva, Breuer et al. 2014). In PRIME we used the ToC to identify common indicators for each ToC outcome across each of the five PRIME countries. This in turn informed the design of evaluation, which allowed the programme to be compared across all PRIME sites (De Silva, Rathod et al. 2016).

7) *ToC indicators may need to be prioritised to account for time and resource constraints*

It is unsurprising that the ToCs of complex programmes are complex with many outcomes, causal pathways and feedback loops. The ToC maps can result in a comprehensive evaluation plan which is made up of multiple study designs collecting various types of data. If resources are limited, it may be necessary to prioritise key indicators within the ToC so that the study designs are focused on collecting data on the most important steps along the causal pathway.

8) ToC does not prescribe a data collection method

ToC provides a framework to identify the pathways to impact but it does not prescribe the type of data collection or analysis (Connell and Kubisch 1998). This allows for the use of a wide range of quantitative and qualitative data collection and analysis techniques such as surveys, in depth interviews, document reviews, cohort studies, nested randomized controlled trials, or programme observation (Breuer, Lee et al. 2016). Data for the PRIME ToC indicators were collected using four study designs: repeat community surveys; repeat facility detection surveys; cohort studies; and case studies (De Silva, Rathod et al. 2016).

9) Combining data to evaluate indicators for short-, medium- and long- term outcomes is possible

In a recent systematic review we found that many ToC data analysis techniques evaluate each outcome separately and do not combine the evaluation of the short-, medium- and long- term outcomes of the ToC (Breuer, Lee et al. 2016). Methods that show promise for an integrated analysis of indicators in the ToC for complex mental health interventions are comparative case studies (Mookherji and LaFond 2013), Qualitative Comparative Analysis (Kane, Lewis et al. 2014) or statistical approaches such as path analysis or structural equation modelling (Adedokun, Childress et al. 2011). Comparative case studies allow in-depth comparison of cases but become difficult to compare as cases increase. A conceptual limitation of structural equation modelling and other statistical techniques is the reduction of contextual factors to variables. ToC, as part of the broader school of theory driven enquiry, is interested in "what works for whom in what circumstances". A reductionist statistical approach may be useful in understanding key causal mechanisms but may

obscure some of the complexity related to context and other factors which co-vary between contexts. In PRIME, we have used a Qualitative Comparative Analysis approach to analyse data from ToC indicators from Nepal and will present this in a subsequent paper. Qualitative Comparative Analysis is a case orientated approach which uses set theory and Boolean logic to understand patterns across cases (Kane, Lewis et al. 2014) and holds promise for analysing ToC indicators in mental health services research.

10) A ToC from a programme can be used as a heuristic device which can be adapted for other similar contexts

Where a ToC has already been developed, it can be used to inform other ToCs for similar programmes (Funnell and Rogers 2011). Our PRIME ToC had a lot of similarities to ToCs developed in other similar mental health programmes, for example the Friendship Bench in Zimbabwe and the RISE project in Ethiopia (De Silva, Breuer et al. 2014, Asher, Fekadu et al. 2015, Breuer, De Silva et al. 2016, Chibanda, Verhey et al. 2016). ToCs developed for one programme could be used as a heuristic device to adapt for other programmes. Care should be taken to ensure that the requisite contextual information and stakeholder input is obtained during this process to ensure that the ToC is adequately adapted to the new setting.

6.1 Conclusion

In summary, ToC, if applied thoughtfully and consistently, can be of great help in understanding complex interventions and strengthen the approach suggested in the MRC guidance for complex health interventions (Craig, Dieppe et al. 2008). Where resources are

available to conduct ToC workshops, it offers a flexible approach to develop a complex intervention. It provides a comprehensive way to identify indicators to measure the short-, medium- and long- term outcomes on the pathway to impact. Indicators can then be prioritised if required and evaluation designs developed accordingly. Various data analysis approaches such as Qualitative Comparative Analysis show promise to evaluate indicators from the ToC.

6.2 Declarations

6.2.1 Financial Support

This study is an output of the Programme for Improving Mental health care (PRIME). This work was supported by the UK Department for International Development [201446]. The views expressed do not necessarily reflect the UK Government's official policies.

6.2.2 Conflict of Interest

None.

Chapter 7. Discussion

This chapter summarises the findings of the thesis. First, I will discuss the findings in relation to the aim of the thesis, namely, to critically appraise how ToC was used as a comprehensive approach to guide the design and evaluation of the PRIME Mental Health Care Plans, how these findings contribute to the research literature on designing and evaluating complex health interventions and how this compares to other relevant approaches. I will then reflect on the contributions of this thesis to the theoretical aspects underpinning the design and evaluation of complex health interventions and the role of context. Implications for policy and practice will be presented followed by the limitations of the research and areas for future research. Finally, the conclusions from the thesis will be presented.

7.1 Summary of findings and relation to literature

7.1.1 ToC and complex health interventions

In this thesis I showed a concrete example of how ToC can be used as a participatory approach which allows the co-development of programme theories with various stakeholders who understand the context. I also showed how these programme theories can be used to develop interventions and evaluate them. I reflect on the main findings in relation to the literature on ToC and complex interventions below. In order to orientate the reader, I have highlighted the key findings and their chapter number in bold.

7.1.1.1 ToC in the public health intervention literature

In the systematic review in Chapter 2, I found that **developing ToC for, or using ToC in the design and evaluation of public health interventions is not new.** I found sixty-two accounts of ToC published in the peer-reviewed or grey literature up until December 2013. The first publications were published in 1999. This was surprising as it is significantly more than the systematic review published by to Coryn and colleagues (2011). Of the 45 examples of Theory Driven Evaluations included in Coryn's review, 21 were public health interventions and three of those used ToC specifically. The most likely explanation is that they excluded papers which did not provide enough detail. In Chapter 2, I showed that 49/62 (79%) described how the ToC was developed, 18/62 (29%) how the ToC was used to inform the development of the interventions and 49/62 described the role of ToC in the evaluation of the intervention.

I showed that the use of ToC was increasing over time (Fig 2.2). Since the systematic review was conducted, there have been several additional papers related to ToC which have been published. A repeat search conducted on the 8th November 2017 showed an additional 172 abstracts which would have been included in the abstract review. This included several papers which have specifically described using ToCs in relation to the development and evaluation of complex mental health interventions in low and middle income countries (De Silva, Breuer et al. 2014, Asher, Fekadu et al. 2015, Asher, De Silva et al. 2016, Chibanda, Verhey et al. 2016).

The systematic review showed that **there is a lack of clear description of the use of ToC in the literature on public health interventions (Chapter 2).** In contrast to Coryn and

colleagues (2011), I included all papers which claimed to use ToC. However, I found the amount of detail provided varied considerably. Some papers, such as Basson and Roets (2013) and Hernandez and Hodges (2006), provided a detailed description of the ToC process and use but many papers only included a brief reference to ToC. They often did not describe the development of the ToC or show how it was used to inform the intervention or the subsequent evaluations.

As a result, I proposed a checklist for the reporting of ToC based on the review. This could be used for any paper using ToC in different stages of intervention development or evaluation. The checklist can be used with other checklists for established study designs such as the CONSORT statement for randomised controlled trials (Schulz, Altman et al. 2010) or CReDECI for complex interventions (Möhler, Köpke et al. 2015).

7.1.1.2 ToC in the design of complex health interventions

In Chapter 3, I showed how **ToC workshops can be a used to collaboratively design complex health interventions.** Using a framework analysis of stakeholder interviews and process documentation from 13 ToC workshops, I showed how the PRIME ToC workshops contributed to the development of a logical, structured ToC map, a contextualised MHCP and stakeholder buy-in. I found that in the workshops, stakeholders worked together to develop the ToC, make explicit the anticipated causal pathways and refine these pathways as a group. This process led to a contextually appropriate and feasible MHCP with clearly articulated assumptions. Chibanda, Verhey et al. (2016) also describe how they used eight ToC workshops over a six month period to develop the Friendship Bench intervention in Zimbabwe. The ToC workshops focused on four key phases of the intervention: formative

work, piloting, evaluation using an RCT and scale-up. Similar to this thesis, Chibanda and colleagues found the participatory process of the ToC workshops was a good way to involve stakeholders in the planning of the intervention, and to achieve buy-in for scale up.

Although ToC workshops are often recommended as a participatory approach to ToC development (Connell and Kubisch 1998), the systematic review of the literature presented in Chapter 2 showed a range of approaches which were used to develop ToCs. These include workshops and working groups, document reviews, interviews and discussions, surveys, programme observation, literature reviews and existing conceptual frameworks. Many of the approaches are used together and at different stages of the ToC development process. None of the studies included in the systematic review in Chapter 2 compared different approaches to develop ToC or conducted interviews with workshop facilitators. Therefore, Chapter 3 is an important contribution to the literature as it synthesises the experiences of the facilitators across a number of workshops in a number of different settings.

Different stakeholders at the workshop contribute different types of information to the ToC process (Chapter 3). The presence of multiple stakeholders including mental health specialists, researchers, policy makers, district level health planners and management and service providers ensured that the stakeholders could provide content on all the areas required for the development of the ToC. This included the level of existing mental health services, human resources available, space and financial resources, clinical knowledge about identification, treatment and recovery of mental illness, the evidence base underlying effective treatments and monitoring and evaluation of programmes.

The presence of these stakeholders during the workshops ensured ownership and buy in of the ToC and MHCP. The systematic review in Chapter 2 highlighted the importance of stakeholder consultation or interviews in ToC development which included management, programme staff, experts, families, service users and evaluators. Sullivan and Stewart (2006) point out that the way in which the ToC is developed influences the extent of ownership of the ToC therefore the level of engagement and type of ownership should be decided on *a priori*.

The hierarchies within the health system are an important consideration for ToC workshops as power dynamics are likely to influence the functioning of the group (Chapter 3). This was anticipated by the facilitators prior to the workshops. As a result, PRIME ToC workshop facilitators took these into account by 1) stratifying stakeholders into different workshops; 2) limiting participants to a homogenous group; or 3) obtaining input and buy-in through other fora, such as interviews. Chibanda, Verhey et al. (2016), also stratified workshops to ensure participation and buy-in from a range of stakeholders for the Friendship Bench counselling intervention in Zimbabwe.

A comprehensive cross country ToC process can result in a programme theory which is relevant for complex multilevel intervention in different contexts (Chapter 4). The three stage process used in PRIME involved 1) the initial development of a cross country ToC in a ToC workshop; 2) using ToC workshops to develop country specific ToCs; and 3) refinement of the cross country ToC. During this process, other PRIME partners gave input via email, through reviewing the ToC at a PRIME partners meeting and by comparing and learning from each country ToC.

The resultant cross country ToC for PRIME and five country specific ToCs provided programme theories which were relevant both within and across countries. Mookherji and LaFond (2013) is the only other study I found in the review which describes ToC development for multilevel complex health interventions across low resource settings. The lessons from this experience are already being used by other projects including Indigo-Primary project which is using ToC to assist with developing and evaluating interventions which improve knowledge, attitudes and behaviour of primary care staff towards people with mental illness in primary care settings (The Indigo Network 2018). They plan to develop their interventions using various approaches including situational analyses, literature reviews and ToC. Both cross country and country ToCs will be developed using workshops and this will inform the development and evaluation of the intervention. Another project, Strengthening responses to dementia in developing countries (STRiDE) is also using the lessons from PRIME to develop a ToC across multiple contexts (Research Councils UK 2018). In addition to a situational analysis, ToC workshops will be conducted both across and within each country and both country and cross country ToCs will be produced. The ToC will be used to inform the development of a research and training agenda to fill knowledge and training gaps for dementia care and financing in seven countries. In addition, the cross country ToC indicators will be used to develop a logframe for the monitoring and evaluation of the programme.

An important finding of this thesis in relation to complex health interventions is the success in using ToC to develop similar interventions and evaluation designs across settings with the **ToC providing a framework to map contextually relevant interventions (Chapter 4).** Intervention developers and evaluators are becoming increasingly aware of ensuring that

interventions are contextually relevant. In 2004, Hawe, Shiell et al. (2004) proposed that this could be overcome by focusing on the function rather than the form of the intervention. However, it was not clear how to operationalise this systematically across multiple settings. In Chapter 4, I show how the development of a cross country ToC provides an approach which ensures that the interventions have the same functions but can be developed locally to be contextually relevant. This allows significant autonomy in each of the sites to develop their own interventions. As the function of the intervention is the same, the evaluation can focus on determining whether the intervention achieved its outcome. During the PRIME cross country ToC development, the interventions were mapped on as functions. A matrix of core and optional functions was developed. The functions were then operationalised in each setting. For example, instead of "screening for depression using PHQ-9" the function was "identification of people with depression". In the first, the specific form of the intervention was described which may not be appropriate or evidence based in all contexts. Describing the intervention as a function provided the flexibility for each country to determine the form of their own interventions to achieve each function.

Although prescribing the function but not the form across countries provided the ability to develop contextually relevant interventions to achieve each function, there were some disadvantages inherent in this approach. The first is that the interventions were developed mostly independently and so there were no economies of scale. Secondly, because both the interventions and contexts differed, direct comparison across settings is difficult.

Additional approaches to develop the interventions included situational analyses, qualitative interviews with district managers, service providers and people living with mental illness, costing of the interventions and piloting. Therefore, **ToC should be seen as a**

complement to other methods used for intervention development (Chapter 4). Using a combination of intervention development approaches resulted in a detailed MHCP with detailed training manuals and the roles of human resources (Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Kigozi, Kizza et al. 2016, Petersen, Fairall et al. 2016, Shidhaye, Shrivastava et al. 2016). However, ToC is the only one of these approaches which seeks to explicitly co-develop the content and implementation process of the intervention with stakeholders. Although 18/62 papers included in the systematic review described using ToC to design their intervention, this was usually in the form of a framework or strategic plan (Chapter 2). There was little detail on how to operationalise the ToC into a plan. I show how using the ToC approach can used together with other intervention development approaches.

This was echoed by a more in-depth paper on the PRIME ToC process and resulting ToC in Ethiopia published by Hailemariam, Fekadu et al. (2015) and colleagues. There we describe the process of how the ToC was developed through workshops with a total of 46 stakeholders. We found that the workshops were important to achieve political commitment and awareness. However, we found that other approaches such as follow-up interviews were necessary to elicit the required detail to complete the MHCP.

Asher and colleagues used ToC in the development of a community based rehabilitation intervention for people with schizophrenia in Sodo, the PRIME implementation district in Ethiopia (Asher, Fekadu et al. 2015, Asher, De Silva et al. 2016). They used a situational analysis, individual interviews, focus group discussions and literature reviews in addition to ToC workshops (one with experts and one community workshop) to develop the intervention which was subsequently piloted and evaluated using a cluster RCT.

Lessons learned from the ToC development process could be transferable to other intervention development approaches. These include the PREPARE-PROCEED model (Crosby and Noar 2011), RE-AIM (Glasgow and Estabrooks 2018), participatory impact pathways (Ekirapa-Kiracho, Ghosh et al. 2017) and other theory driven approaches to evaluation such as logic modelling. To my knowledge, there has not been any direct comparison of these approaches, however, O'Cathain and colleagues have recently been awarded funding from the Research Council of the UK to map and critique approaches to develop complex interventions (Research Councils UK 2018). This research should assist both with the understanding of the approaches and transferring lessons learned between similar approaches.

7.1.1.3 ToC for the evaluation of complex health interventions

ToC can be used to identify indicators for the short-, medium- and long-term outcomes (Chapter 4). As part of the ToC development process, I showed how indicators were developed for each of the ToC short-, medium- and long-term outcomes. In addition, additional input, process and output indicators were developed for the MHCP functions in each country. These were then incorporated into protocols for four different study designs to measure the implementation of the programme by the PRIME consortium (De Silva, Rathod et al. 2016). These study designs were a community survey, a facility detection survey, a cohort study and case study. The development, country adaptation, data collection, data cleaning and data analysis of these study designs were not part of this PhD.

In Chapter 4 I showed that the advantage of using a ToC was that the causal pathway was made explicit and the indicators were developed to measure each step along the pathway.

This occurred prior to the development of the protocol and ensured that all the key outcomes along the hypothesised causal pathway were measured. As suggested by Moore, Audrey et al. (2015) in the MRC guidance on *Process evaluation of complex interventions*, this ensured that PRIME collected information on 1) to what extent the MHCP was implemented; 2) whether and through what mechanism of change the MHCP achieved its stated outcome; and 3) the contextual factors affecting implementation. Because the evaluation design was developed to measure the function of the intervention, rather than the form, the same evaluation could be used across all five countries, despite the differences in the forms of their MHCPs. This is similar to the approach taken by Chandani, Noel et al. (2012) who used the ToC to evaluate factors affecting essential medication supply by community health workers in Ethiopia, Malawi and Rwanda. Asher (2017) also used the ToC to develop indicators to pilot test a community based psychosocial rehabilitation intervention in Ethiopia, and explore the interventions' feasibility, acceptability and effect on functioning. The results of the pilot study were used to refine the ToC and the assumptions in preparation for a cluster randomised controlled trial (Asher, Silva et al. 2016).

Despite the development of cross country indicators, the ways these were operationalised in each country varied, making direct comparison difficult at times. For example, in the PRIME community survey, the question relating to treatment for probable depression or alcohol use disorder in India, Nepal and Uganda used a recall period of 12 months whereas in Ethiopia the recall period was "ever" (Rathod, De Silva et al. 2016). This hampered the comparison of treatment coverage across countries. Other differences in the ways the indicators were operationalised, such as differences in follow up periods between countries,

also influenced the ability to compare across study countries. Therefore, although the adaptation of study designs and questionnaires for each context are essential to ensure relevant data, some standardisation of the data collection for key indicators may be necessary to ensure cross country comparison.

No studies in the systematic review in Chapter 2 used a quantitative approach to explicitly combine outcome and process data from ToCs, although it has been used elsewhere. For example, Adedokun, Childress et al. (2011) used structural equation modelling to test the ToC data from an undergraduate internship programme. A recent study by Anselmi, Binyaruka et al. (2017) used ToC and used a structural equation model to determine the mediators of a pay for performance programme on the improvement in maternal care outcomes in Tanzania. Similarly, Asher is also proposing using ToC as a framework for conducting a mediation analysis to test the hypothesised causal pathways in the ToC in her randomised controlled trial on community based rehabilitation for people with schizophrenia in Ethiopia (Asher 2017).

Quantitative approaches allow the analysis of data from large datasets and aim to find the active ingredients in the complex interventions. However, there remain some fundamental challenges with statistical approaches combined with ToC, particularly with respect to using these to evaluate health service interventions. Firstly, the sample size requirement is often high. For example, the PRIME ToCs were developed at district level, and each country only has one implementation district. Even if they were developed at facility level, the sample size would have been a challenge with only 3-14 implementation facilities in each country. Secondly, statistical approaches often reduce contextual variables to control variables

rather than “what works for whom in what circumstances” which is the underlying philosophy of theory driven evaluation (Pawson 2003).

QCA can be used to analyse process and outcome data in a single analysis in health services research (Chapter 5). As discussed in Chapter 5, QCA is an approach that can be used to combine process and outcome evaluation. It was developed as an extension to comparative case studies and uses Boolean logic rather than statistics to find patterns in the data. It can use a combination of qualitative and quantitative data from small to medium numbers of cases. A fundamental principle of QCA is conjunctural causation, i.e. that multiple causes can act together to result in the outcome. This is unlike statistical approaches which examine the effect of one cause on the outcome and need to eliminate all other confounding variables in the analysis. Determining how multiple intervention components is important to unpack the black box of complex health interventions. In Chapter 5, I provided an example of how QCA can be used together with ToC to provide an analysis of processes and outcomes using routine health services data. Although QCA has been recommended for health service and translational research (Kane, Lewis et al. 2014), there are only a few examples in the health service literature (Sheehy and Thygeson 2014, Siltanen, Aromaa et al. 2014, Warren, Wistow et al. 2014, Goicolea, Vives-Cases et al. 2015, McAlearney, Walker et al. 2016, Walia, Belludi et al. 2016, Kane, Hinnant et al. 2017) although they are increasing. None of these combined using QCA with ToC. In Chapter 5, I show how it is possible to combine ToC and QCA to combine process and outcome evaluation using routine health services data.

7.1.2 Comparisons with other approaches relevant to the design and evaluation of complex health interventions

ToC in conjunction with the MRC framework on complex interventions as used in PRIME contributed to the development, to the implementation (specifically the evaluation thereof), the evaluation, stakeholder participation, understanding causal pathways and the inclusion of context. However, without a counterfactual, it is difficult to determine how the PRIME MHCPs would have been developed and evaluated without using ToC as an approach to guide this process. However, it is possible to conduct a thought experiment with related approaches which have been used to inform the development or evaluation of complex health interventions. In Table 7.1 and below, I have compare some of these approaches according to the extent to which they contribute the four MRC Guidance on Complex Intervention domains (intervention development, feasibility/piloting, implementation, and evaluation), stakeholder participation, understanding causal pathways and the role of context. This is a crude comparison as it was conducted using standard application of the theory, framework, model or approach and not based on an in depth review of the approaches and assumes they were used in isolation.

Table 7-1 Approaches relevant to design, implementation and evaluation of complex health interventions and the extent to which they cover the included domains.

Theoretical perspective	Theory/framework/model/approach	MRC Guidance on Complex Interventions Domains				Stakeholder participation	Understanding causal pathways	Inclusion of context
		Intervention development	Feasibility/piloting	Implementation	Evaluation			
	Theory of Change as used in PRIME							
Evidence based healthcare	Revised MRC guidance on Evaluation of Complex Interventions (Medical Research Council 2008)							
	MRC guidance on process evaluation for complex interventions (Moore, Audrey et al. 2015)							
Theory Driven Evaluation	Realistic evaluation (Pawson and Tilley 1997)							
	Logic model (Funnell and Rogers 2011)							
	Logframe (Wildschut 2014)							
	Theory of Change (Connell and Kubisch 1998)							
Implementation Science Implementation	Conceptual model of diffusion of innovations (Greenhalgh, Robert et al. 2004)							
	Normalisation Process Theory (May, Mair et al. 2009, Murray et al. 2010)							
	Organisational readiness (Weiner 2009)							
	Integrated general theory of implementation (May 2013)							
Classic theories	Complexity Theory (Plsek and Greenhalgh 2001, Paina and Peters 2012)							
Public health	RE-AIM (Glasgow, Vogt et al. 1999)							
	PRECEED-PROCEED (Green and Kreuter 1999)							

Dark red: this is a key focus of this theory/framework/model/approach; Light red: sometimes or occasionally mentioned or used; White: never or rarely used or mentioned

Most similar to the ToC approach is the PRECEED-PROCEED developed by Green and Kreuter (1999) for public health interventions. The PRECEED-PROCEED model describes a detailed framework for the planning and subsequent evaluation of an intervention. Prior to intervention development there is a detailed social, epidemiological, behavioural, environmental, educational and ecological assessment and the interventions are based on the contextual assessment and are aligned with existing policies. The model provides a generic programme theory for health interventions can be adapted by the programme which is developed through backward mapping by stakeholders. It includes descriptions of the implementation and process evaluation and helps to plan both outcome and impact evaluations.

The PRECEED-PROCEED model shares many of the aspects of the ToC approach including understanding the context, making clear the causal pathway and providing a programme theory. However, the generic programme theory and the contextual assessment is based primarily on community health promotion programmes and less on programmes within the health services like PRIME and therefore would need adaptation to make it programme specific. In contrast, the ToC approach is more flexible and allows for a programme theory to be developed for any situation with the content driven by the developers of the ToC. The disadvantage of this is that important elements of both the contextual assessment and the programme theory could be missed. In PRIME, we mitigated this risk by undertaking a systematic process of ToC development with a wide range of participants including experienced researchers, implementers and policy makers across and within countries.

Realist evaluation is approach within the field of Theory Driven evaluation (Pawson and Tilley 1997). Realist evaluation philosophical roots in critical realism and is mostly used in

post-hoc evaluation. The focus is primarily on developing, testing and refining causal pathways which are seen as the interplay between context, mechanism and outcome. Unlike the approach we used in PRIME with ToC together with the MRC guidance on complex health intervention, there is no specific guidance on intervention development or implementation. Realist evaluation focuses much more specifically on developing and refining theories of existing programmes to understand how the intervention results in outcomes and seeking to understand "what works for whom in what circumstances" (Pawson and Tilley 1997). In contrast, most of the practical guidance on the ToC approach focuses on the development of the ToC and less on refining of the programme theories. In addition, because of the scope of the PRIME ToC, the theory of how each intervention component might work for each step in the PRIME ToC (as represented by the arrows) has not been made explicit. As the PRIME evaluation results for the whole of the PRIME ToC are finalised, the generative approach to theory building and testing from realistic evaluation could be used to further develop the PRIME ToC by considering context, mechanism and outcome configurations for each step in the PRIME ToC.

The Implementation Science theories and frameworks are concerned primarily with how to implement interventions rather than evaluate them for effectiveness. For example, Normalisation Process Theory sets out a theory of whether and how an intervention could be embedded and sustained in routine practice (May, Mair et al. 2009, Murray, Treweek et al. 2010). A targeted intervention could be developed and implemented which incorporates these features. However, Normalisation Process Theory does not focus on the practicalities of how the intervention should be developed or what approaches could be used to evaluate it. Normalisation Process Theory could be used within a programme specific ToC to improve

the likelihood that the intervention would be successfully implementation, embedded and sustained in routine practice.

Lastly, complexity theory is an example of a classic or grand theory which could be used to understand the behaviour of interventions as part of a complex system. However, it does not give a practical guidance on how an intervention can be developed, implemented and evaluated. Using complexity science together with ToC to inform the intervention and evaluation could result in a more nuanced and less linear outline of the programme which is more able to capture the unpredictable nature of the outcomes.

In summary, the ToC approach used within PRIME and described in this thesis provides an approach to develop programme theory to inform interventions and provides a structured framework for evaluation. There is a specific focus on understanding causal pathways which is lacking in the MRC guidance on developing and evaluating complex interventions, logframes and logic models and provides more detail on the intervention development and evaluation than implementation science theories. However, using other approaches could further strengthen the ToC. For example, considering complexity theory in the planning of interventions, normalisation process theory in assessing the sustainability of the intervention and a realist approach to refining programme theories could strengthen the current approach further.

7.2 Contribution to theory

There has been significant growth in the field of complex interventions since the publication of the MRC guidance on complex interventions in 2008. In the guidance, Craig, Dieppe et al. (2008) recommended using theory to inform the development of complex interventions.

Since then, Moore, Audrey et al. (2015), have echoed the recommendation on using theory in the MRC guidance on process evaluation. However, Moore and Evans (2017) caution both against using "off the shelf" theories to develop interventions as well as individual-level theorising of systems-level problems. Instead, they propose the development of a clear understanding of the problem in context and the systems into which complex interventions will be implemented. They argue that the co-production of the intervention with stakeholders who understand the context is most likely to be effective, especially when implemented in complex health systems. Hawe (2015) recommends that carefully developed *a priori* programme theories are important to assess complex interventions prior to implementation. In parallel in the field of Implementation Science, Nilsen (2015) argues that implementation science researchers should use theory from implementation science, psychology, sociology to inform their research but does cautions that using a single theory may not be adequate to describe all aspects of implementation. Van Belle, van de Pas et al. (2017) take this further by cautioning against poorly selected existing theories and advocates for theory building Implementation Science. They argue that research can be used to develop middle-range theories which can then be applied, tested and further developed in other settings thus building on existing knowledge.

In this thesis, I have provided a methodological contribution by showing an approach which can be applied the development and evaluation of complex health interventions. Namely programme theory which formalises the process of stakeholders' implicit theories of the programme and allowing this to be strengthened through formal theories from social sciences, psychology, organisational theory or implementation science.

As argued by Hawe (Hawe 2015), this allows the programme theory to be critiqued, adapted and changed by others interested in implementing similar programmes. It also provides multiple hypothesis for how the components of the programme are predicted to work and will be tested through both quantitative and qualitative approaches in the evaluation of PRIME.

7.2.1 Towards a middle range theory for improving coverage of (mental) health services

Although still a programme theory, the PRIME ToC can form the start for the development of a middle range theory for the integration of mental health into primary health care. It was developed across five contextually different settings with a range of diverse stakeholders. Although the PRIME ToC did not explicitly contain references to theories from social science, there are several theories relevant to global mental health which are implicit in the ToC. These include the Tanahashi model of health services coverage (Tanahashi 1978), models of access to healthcare (McIntyre, Thiede et al. 2009, Levesque, Harris et al. 2013), the Donabedian model (Donabedian, Wheeler et al. 1982) and Thornicroft and Tansella's mental health matrix (Tansella and Thornicroft 1998).

The PRIME ToC draws heavily on the Tanahashi model of health services coverage (Tanahashi 1978). The Tanahashi framework underpins thinking on global mental health which aims to increase the equitable coverage of services (Patel and Prince 2010, De Silva, Lee et al. 2014). Tansahashi describes five levels of coverage of health services: 1) Availability, 2) Accessibility 3) Affordability 4) Contact and 5) Effective (Figure 7.1). The PRIME ToC operationalises this framework by adapting this to mental health and by providing specific indicators for the measurement of all five levels of coverage, albeit in a

slightly different order. This is illustrated in Figure 7.2 where the ToC is overlaid with the levels of coverage from the Tanahashi framework.

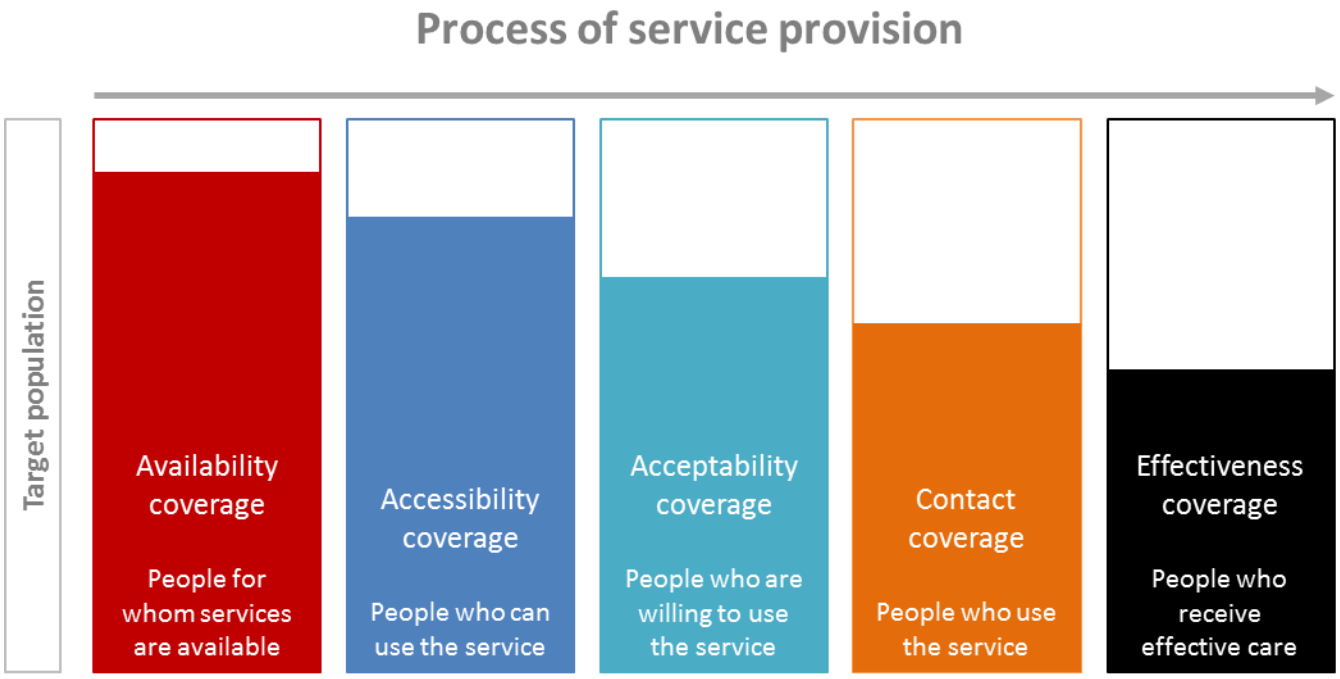
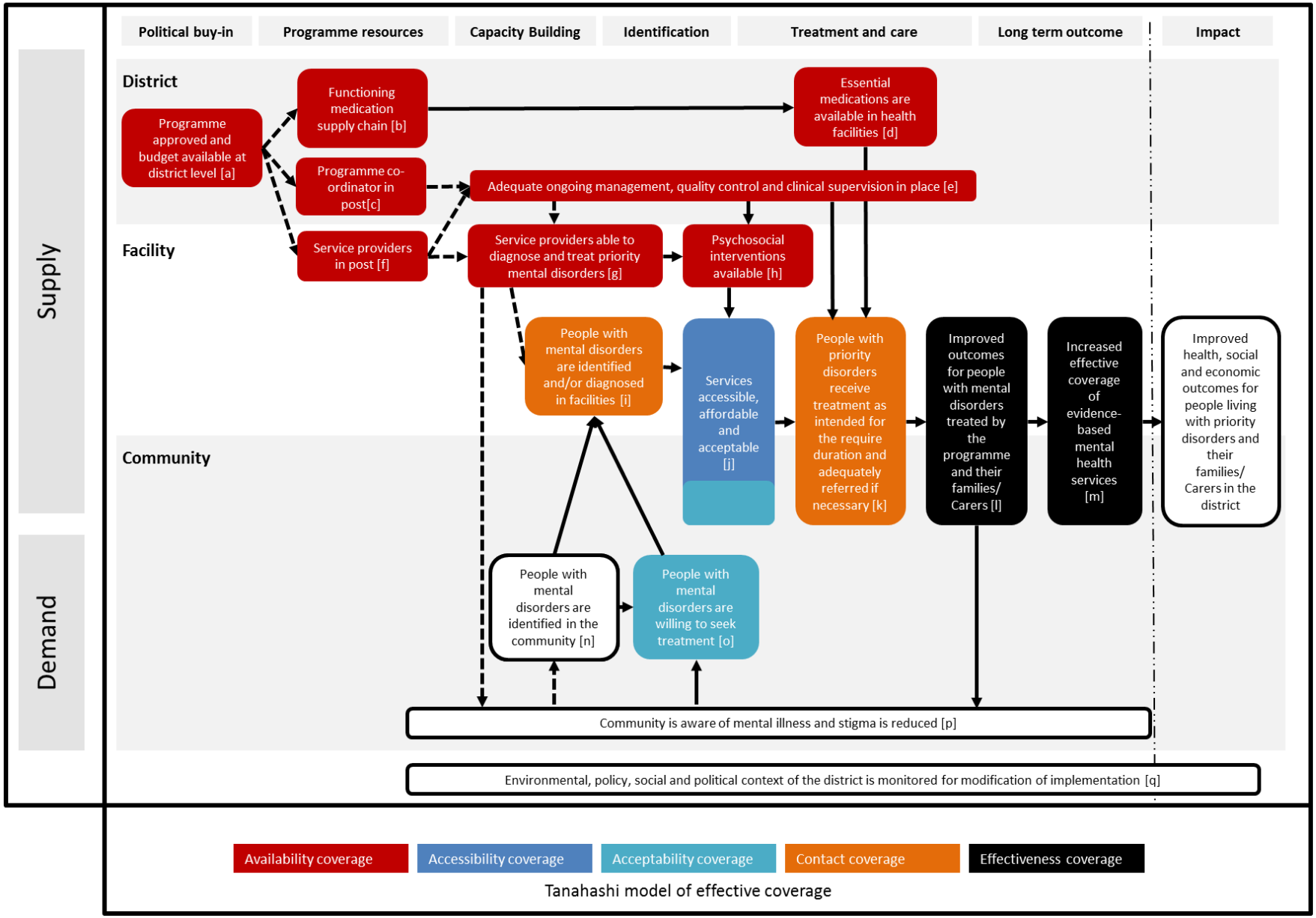


Figure 7-1 Tanahashi model of health services coverage. Adapted from Tanahashi (1978)

In addition, the expertise of the stakeholders ensured that the PRIME ToC incorporates elements of health services research frameworks, for example, conceptualising health service access as resulting from both demand and supply side factors (McIntyre, Thiede et al. 2009, Levesque, Harris et al. 2013) (Figure 7.2). Other relevant models which are reflected in the PRIME ToC are the Donabedian model which posits that quality healthcare is dependent on the structure, process and outcomes of a health service (Donabedian, Wheeler et al. 1982).



Tanahashi model of effective coverage

Figure 7-2 The PRIME ToC and the five Tanahashi levels of coverage

In mental health services research Tansella and Thornicroft (1998) extend the Donabedian model, conceptualise mental health services as having a temporal dimension with inputs, process and outcomes. However, they add a geographical dimension which distinguishes between individual, local level and country/regional level for each of these temporal dimensions. The PRIME ToC focuses on three levels but separates out the facility from the community level and does not consider the country/regional level. A formal comparison of the PRIME ToC and the mental health matrix may strengthen the ToC.

The PRIME ToC is complex and this thesis only tested a part of the programme theory in one country. In Chapter 5, I provided a case example of a method to analyse the relationship between programme inputs and routine service utilisation data to understand the "active ingredients" of the PRIME MHCPs. Specifically, I aimed to determine what combination of conditions at community and facility level identified in the PRIME ToC influenced service utilisation in the PRIME implementation facilities in Nepal. I used pooled QCA to conduct a longitudinal analysis of service utilisation in the clinics at each time point. The short- and medium- term outcomes identified in the ToC were used as condition sets in the QCA analysis. I found that the presence of psychosocial care, mhGAP, referral to services and combination of supply and demand side factors were necessary but not sufficient for high service utilisation in the PRIME implementation facilities in Nepal. In addition, two additional causal pathways were identified as sufficient and these included both supply (medication supply, trained staff) and demand side factors (frequent use of CIDT and larger proportion of the community attended awareness activities). Similarly, low service utilisation was also related to a combination of both supply (lack of facility and community

supervision, lack of MhGAP service) and demand side factors (low participation in community awareness activities). This shows the multiple interventions required both to improve services and increase demand in order to ensure service utilisation for mental health increases at facilities. This supports the recommendation outlined in the PLoS series on packages of care for Mental, Neurological and Substance Use Disorders which recommends that a combination of packages including case finding and assessment, and psychosocial and pharmacological treatment are necessary for integration of mental health into primary healthcare, supported by training and supervision (Patel and Thornicroft 2009). However, results from other countries should be used to understand whether this is true across countries. In addition, results from the evaluation studies in PRIME can help to understand what worked in which context.

This PRIME ToC can be bas a potential heuristic device which can be adapted and used in other programmes aiming to integrate mental health into primary healthcare. The ToC will need to be evaluated further using the results of the PRIME evaluation in order to establish that the PRIME ToC does adequately outline the causal pathways required to achieve the outcome. The ToC should then be adapted based on the revised understanding of the causal mechanisms and draw on other ToCs which have been developed. For example, a ToC developed for a counselling intervention for maternal depression delivered by community health workers in Pakistan by the South Asian Hub for Advocacy, Research and Education on mental health (SHARE) (De Silva, Breuer et al. 2014) or for a community based rehabilitation intervention as part of the Rehabilitation Intervention for people with Schizophrenia in Ethiopia study (RISE) (Asher, Fekadu et al. 2015) and the Friendship Bench (Chibanda, Verhey et al. 2016). If this ToC is tested in other settings and refined, it may be possible to

advance and build upon the ToC in order to develop a middle range theory for the integration of mental health into primary healthcare.

In summary, I have provided a methodological contribution at the intersection of Evidence Based Medicine, Theory Driven Evaluation and Global Mental Health. Specifically, I have shown how ToC can be used to develop programme theories in a participatory way which can then be used as a framework for evaluation. Although Hawe (2015), Moore and Evans (2017) and Van Belle, van de Pas et al. (2017) argue for this, I have provided a concrete, practical example of how this can be done across several diverse contexts and provided a starting point for the development of a middle range theory on the integration of mental health into primary healthcare.

7.3 The role of context

This thesis shows how ToC can be used to strengthen the MRC Guidance on the Evaluation of Complex Interventions across diverse contexts. Understanding context is essential in global mental health. This is because the concept of mental illness, symptoms, aetiology and perceived effective treatments are inextricably linked with culture and society (Kleinman 2004). For example, an intervention developed for a rural area in Uganda may not be culturally appropriate or feasible in a semi-urban setting in South Africa. This is in addition to the contextual differences between health services and systems encountered in complex interventions research. As I outlined in Chapters 3 and 4, ToC provides a way to ensure that programme theories and interventions are developed with stakeholders in a contextually relevant way. This is particularly important amidst criticism that global mental health is

exporting western understandings of mental illness and their treatments to LAMIC (Summerfield 2013).

As described in Section 4.6, despite the diversity of settings and resources in the PRIME countries, the causal pathways in the ToCs were quite similar across countries. There were some differences in the outcomes included. For example, in India the workshop participants stressed the importance of the development of a mental health space within the health facility to co-ordinate the services across facilities. In Nepal, the management of adolescent depression was seen as a key outcome. In South Africa, medication supply was not included as an outcome but as an assumption because the existing supply chain was thought to be functioning adequately.

The similarity across countries is likely due to several reasons. The first is that all the PRIME country workshop facilitators were part of the initial ToC development workshop in Goa, India. Therefore their implicit ToCs were likely to be similar. In addition, the facilitators had been part of the grant writing team for the original PRIME proposal which outlined the aim of the programme as well as the principles which guided the programme, namely (a) a focus on health systems strengthening; (b) working in partnership with Ministries of Health; (c) prioritising key mental disorders; (d) developing robust frameworks for the design and evaluation of complex interventions; and (e) ensuring equity (Lund, Tomlinson et al. 2012).

Despite the similarity of the ToC maps, the discussions during the ToC workshops were context specific and these helped develop the MHCP packages. For example, in the South African workshop, they used a part of the PRIME cross country ToC and spent time discussing each outcome and how this could potentially occur. There were detailed

discussions on the existing systems and what worked/did not work and what resources could be mobilised to integrate mental health into primary healthcare. For example, in South Africa, there is a university level counselling degree (Bachelor of Psychology in Counselling) which is popular but there are currently no roles within public health service. During this workshop, the need to create roles for these university qualified counsellors was identified. In Nepal, a significant discussion in the workshop was ensuring psychotropic medication availability and various mechanisms to ensure this were suggested by policy makers and implementers.

Therefore, despite the similarities of the ToC maps, the strategies and interventions required in each country to achieve this were quite different. This is reflected in both the diversity and the bottom up development of the PRIME MHCPs (Fekadu, Hanlon et al. 2016, Jordans, Luitel et al. 2016, Kigozi, Kizza et al. 2016, Petersen, Fairall et al. 2016, Shidhaye, Shrivastava et al. 2016) . This resulted in MHCPs which were contextually appropriate. For example, in Nepal, Ethiopia and Uganda, mid-level health workers such as nurses were responsible for the diagnosis and management of routine mental health services, with specialist referral for complex cases. In South Africa and India where more resources were available, initial diagnosis and management of people with people with mental illness was restricted to medical officers in South Africa and medical specialists in India. The MHCPs are compared in detail by Hanlon, Fekadu et al. (2016).

Another difference across contexts was the facilitation of the workshops. Prior to the workshops, a simple guidance document was developed to guide the facilitators with was used together with the Community Builder's Approach to Theory of Change (Andersen 2004) and an introduction on how to use ToC together with the MRC Guidance on

Developing and Evaluation of Complex Interventions (Craig, Dieppe et al. 2008). However, the facilitators could decide on the number and length of the workshops, the stakeholders attending, the agenda of the workshop and the language in which was conducted. This resulted in diversity in how the workshops were structured (Table 3.2) and the participants invited (Table 3.3). Therefore, as described in Chapter 3, where there were likely to be hierarchies within the health system, the facilitators were able to mitigate the effect of power imbalances by stratifying the workshops or limited the participants. The facilitators also ensured that there was the appropriate senior level buy-in, often demonstrated by a senior person introducing the workshop, to add legitimacy.

In all cases, the facilitators were living in the country where the workshops were taking place and were part of the team which was implementing and developing the MHCPs.

This thesis shows that programme theories can be developed across contexts, allowing the evaluation to be based on a common framework. However, the interventions themselves can be contextually driven and based on local needs, resources and evidence. Once the evaluation in all the implementation sites is completed, it will be important to compare these strategies and the extent to which they achieved their outcome to refine the PRIME ToC and inform a middle range theory for the integration of mental health into primary healthcare.

7.4 Implications for policy and practice

This thesis has implications for audiences who are interested in the planning, evaluation or implementation of complex interventions. These include policy makers, NGOs, researchers and funders.

In this thesis, I describe the use of ToC by researchers to develop district specific mental healthcare plans. The lessons from this thesis could also be applied by health service managers to strengthen the design of district health plans. Conducting ToC workshops would mean that stakeholders have the ability to co-develop, modify, adapt and visualise the programme theory. This would ensure that district level plans are contextually appropriate and have the buy-in of all levels of stakeholders and service providers in particular. This is important as service providers who do not agree with a programme may impede the successful implementation of health programmes. This may be remedied by inclusive planning (Walker and Gilson 2004).

However, the ToC process is a complex, time consuming exercise. Therefore, district managers may need training in how to facilitate a ToC process. Training should focus on the core competencies which are needed to facilitate a ToC workshop, namely: 1) understanding the ToC approach; 2) facilitation skills for large groups; 3) ability to think logically and abstractly; 4) ability to understand the broader context and implications of the ToC; and 5) ability to develop indicators. Training could occur face-to-face or utilise the numerous online courses available (Mental Health Innovation Network 2014,(Andersen 2004, Taplin and Rasic 2012, Taplin, Clark H et al. 2013). However, practical experience in conducting ToC workshops and developing ToCs is essential. Follow up and support could

also utilise the communities of practice in the monitoring and evaluation field, such as MANDE-News (Davies 2017) and the Pelican Initiative (Pelican Initiative 2018). Alternately, district planners may choose to employ a facilitator to assist with the facilitation of the workshops. Hernandez and Hodges (2006) describe how public planners have worked together with external facilitators to facilitate the ToC development process. Several examples of ToC being used for district/county level interagency planning for services for at-risk youth in the US were included in the systematic review in Chapter 2 (Hernandez and Hodges 2006, Levison-Johnson and Wenz-Gross 2010, Andersen, Nesman et al. 2012, Levinson-Johnson 2012, Morilus-Black, McCarthy et al. 2012, Wenz-Gross and DuBrino 2012, Illinois Caucus for Adolescent Health 2013).

Non-governmental organisations (NGOs) have frequently used ToC to develop their interventions and strengthen their monitoring and evaluation practice (James 2011, Vogel 2012, James 2013, Valters 2014). Evaluation practitioners often work in tandem with NGOs to strengthen their evaluation design. The findings of this thesis may be useful for NGOs in conducting ToC workshops, using ToCs to develop programme plans and operationalising indicators to measure success. This may strengthen both programme design and monitoring and evaluation of their programmes.

Similarly, funders such as Comic Relief, AusAiD, the World Bank, Grand Challenges Canada and DFID have been using ToC for their overarching programme of work as well as making ToC a requirement for grant recipients (Vogel 2012). This research has strengthened the case for a comprehensive ToC approach that involves stakeholder involvement rather than just as a desk based tool for developing and monitoring programmes. Therefore, funders should continue to allow grantees flexibility in how they use these tools to understand their

programmes in context so that they are not reduced to a results-based management tool (Prinsen and Nijhof 2015, Paina, Wilkinson et al. 2017).

Lastly, this research is relevant for researchers to understand the "black box" of complex interventions. I have shown how ToC can be used to map out the causal pathways of the interventions in order to understand each step. This allows the researcher to test whether the intervention works through these anticipated causal pathways using indicators and then reflect on this in relation to the success of the intervention. Once the ToC has been evaluated, it can be refined and worked upon in further research.

In Box 1, I have outlined several strategies which could be used to increase the use of ToC amongst researchers, policy makers and planners. Despite the benefits of ToC, it may not be appropriate to use ToC for all research projects. As mentioned previously, it is time and resource intensive and needs ongoing time to adapt and change the ToC. This may be difficult due to competing priorities. In Chapter 6, I echo the recommendation in the paper led by De Silva (2014) that a ToC champion is necessary to lead the work through the life of the programme.

Box 1. Strategies to encourage use of ToC

1. Journals which publish the evaluations of complex interventions could require a programme theory or ToC.
2. Funders could encourage the development of programme theories by researchers although allow flexibility in the format and development process
3. Training and mentoring for ToC could be made available through funding agencies

7.5 Limitations

There are several limitations to this thesis, many of which have been mentioned in the discussion sections of the individual chapters. However, seven limitations refer to multiple chapters in the thesis and are therefore worth reflecting on.

The first is that this study as a whole was based on the experience of one project and there is no counterfactual comparison between other approaches to develop and evaluate the PRIME programme. However, I did compare the ToC approach with other potentially relevant approaches to approximate a counterfactual. In addition, I compared and contrasted the use of ToC approaches across contexts. However. these findings may not be generalisable to other settings.

The second is my role within the project and the ToC process. My role could be described as a semi-removed insider. I have been employed as the project manager for the PRIME project based at the University of Cape Town since 2011. As such I was involved in co-ordinating the ToC process together with Mary De Silva. I was involved in the initial cross country ToC development. At the country level I was only involved in the South African ToC workshop, however I provided ongoing support to all countries by providing feedback on the ToC maps. I was responsible for co-ordinating the development and refinement of the ToC map and worked on the development of the indicators. I was less involved in the development of the study designs, and the collection and cleaning of the data. I conducted the analysis for Chapter 5 from the data which was collected as part of the PRIME project in Nepal. My position and location within the project will have biased my experience of the process. I have tried to combat this in various ways by 1) using formal interviews and

qualitative data analysis with facilitators in Chapter 2; 2) including colleagues involved in the ToC processes as co-authors as a form of respondent validation (Mays and Pope 2000) in Chapters 3 and 4 to verify my findings; and 3) working closely with colleagues from Nepal in Chapter 5 to ensure that my understanding of their data was accurate and the interpretation of the findings was plausible.

The third is that the experience of the ToC workshop process was only captured from the facilitators who were part of the PRIME programme. Although feedback was collected from workshop participants in some countries, this was not included in this thesis as it was beyond the scope of the work. However, it would be essential going forward to understand the experiences of the participants in this process and to determine the extent to which participants felt ownership of the process.

The fourth is that the ToC was developed by people from a similar background. Most of the stakeholders within PRIME had a biopsychosocial approach to providing mental health services and would have similar implicit programme theories. As a result, the country ToCs were quite similar. A group of people from other backgrounds may have agreed on a different programme theory.

The fifth is that the PRIME ToC is linear and is likely not capturing the complexity of the programme in context. There are no features of complex adaptive systems in the ToC such as tipping points, feedback loops, emergence or unintended consequences (Glouberman and Zimmerman 2002, Hawe 2015). This may be because many of the complex aspects of the programme were difficult to predict in the absence of similar research on the district level integration of mental healthcare in low resource settings. A more nuanced

understanding of the complex aspects of these systems have emerged during implementation and evaluation of the programmes which has not yet been reflected in the ToC. As mentioned in Chapter 6, the PRIME ToC has not yet been revised for several reasons including waiting for the finalisation of the evaluation and competing research demands. A revision of the country and cross-country ToCs has been planned as part of the evaluation of the MHCPs.

It may be difficult to include features of complex adaptive systems within the ToC map. Asher found that unintended consequences of the intervention were not captured well by the RISE ToC. She also found that the revised ToC became less linear with more bidirectional relationships (Asher 2017). Similarly Paina and colleagues (2017), who used ToC to develop programme theories for health systems interventions in Bangladesh, India and Uganda, found that although their initial ToCs were quite linear, they increased in complexity when they were revised halfway through the programme. Even though linear models may not reflect complexity as well, they still provide a useful model to design the intervention and related evaluation. Further research is necessary to understand how to include features of complex systems such as feedback loops, tipping points and unintended consequences within ToCs.

The sixth is that our cross country ToC did not adequately capture the interaction with the environment and the effect on contextual variables. As expected, these were mostly captured by country specific ToC workshops in the assumptions and therefore not formally included in the cross country research design. As a result only a limited amount of data on contextual factors were collected at a cross country level for PRIME.

The last limitation is that this thesis did not manage to evaluate the ToC as a whole across all five countries. The primary reason for this is that the evaluation of the programme across all five countries is one of the main objectives of the research programme and is therefore being led by the principal investigators of PRIME. The second reason is that the volume of data, data sources and analysis is beyond the scope of a PhD. However, once the analysis for individual outcomes from the ToC have been completed, it should be possible to map the results of the evaluation back onto the ToC in order to determine the validity of the ToC and refine the ToC according to the results.

7.6 Areas for future research

There are several areas which could be considered for future research in relation to ToC and complex mental health interventions. The first is in the reporting of ToC. In Chapter 2, I proposed a checklist for reporting on ToC in the literature. This should be tested on existing literature and modified in consultation with ToC experts before widespread use.

The second area for research is how ToC relates to complex adaptive systems. There is now an increasing interest for programme designers and evaluators to consider complexity theory as a way to conceptualise programmes within complex adaptive systems (Walton 2014, Rutter, Savona et al. 2017). More research is still required to understand how to combine ToC with complexity theory and how to ensure that contextual effects on the ToC are adequately elicited during the ToC development process. This could be informed by other approaches which explicitly engage with context or complex adaptive systems such as outcome mapping (Earl and Carden 2002), realist evaluation (Pawson and Tilley 1997) or community based system dynamics (Trani, Ballard et al. 2016).

The third area of research is how to use ToC in an agile way to inform feasibility, piloting and implementation of complex health interventions (Ling 2012). For example, ToC could be used to develop a dashboard of summary indicators for responsive monitoring during implementation of an intervention. This could involve collecting regular data on the availability of resources and processes required for the implementation of mental health detection and treatment in primary care. The data could be collected on a handheld device with data collection software and summarised with pre-written code in a statistical analysis software such as STATA (Statcorp 2013). This could then be used to provide a real time summary of progress on indicators in order to assess (and intervene) in the implementation of the intervention and inform focus areas for Continuous Quality Improvement approaches to improve services (Wells, Tamir et al. 2017). This approach could be used in the growing field of implementation research which aims to study how interventions can be implemented into routine care (Proctor, Landsverk et al. 2009).

A fourth area of research is how one can use ToC with statistical and mathematical approaches to evaluate programmes and model outcomes. Specifically, more examples are needed to understand how ToC could be used together with statistical models to evaluate health services interventions. This could build on the recent work by Anselmi, Binyaruka et al. (2017), who used ToC as a framework for structural equation modelling to determine the mediators of the effect of a pay for performance programme on maternal health outcomes in Tanzania. ToC could also be used to provide a basis for the mathematical modelling of health services. For example, agent based modelling could be used to predict how individuals interact within a complex system under certain conditions (Maglio and Mabry 2011).

The last area of research is to refine, use and test the PRIME ToC as a heuristic device for the integration of mental health into routine services. This would involve a revision of the PRIME ToC based on the results of the PRIME evaluation and further analysis using QCA to determine the necessary and sufficient components of the PRIME intervention across all five PRIME contexts. The necessary and sufficient components of the ToC could be implemented in other settings and evaluated to determine the generalisability of the programme theory.

Chapter 8.Conclusion

In conclusion, the findings from this thesis contribute to the growing body of knowledge for the use of ToC to develop and evaluate complex health interventions, particularly in the field of global mental health. This thesis supports the proposal by De Silva, Breuer et al. (2014) that the ToC approach can strengthen the MRC guidance for complex health interventions. Specifically, I have shown that in the *design* phase, the ToC provides a clear programme theory which can be reviewed prior to implementation. The participatory approach allows stakeholders' concerns to be articulated and incorporated into the ToC, and the resulting interventions are more likely to be contextually relevant, feasible and acceptable. I showed that the ToC provides a way to operationalise the recommendations by Hawe and colleagues (2004) in standardising complex interventions across settings by function and not form. In relation to the *evaluation* phase, I showed how ToC can provide a clear framework for indicators to measure the short-, medium- and long-term outcomes which can be used to plan the evaluation of the intervention. However, there may be some operational challenges in standardising study designs across countries. I also showed how ToC could be used as a framework to combine process and outcome indicators using QCA. I described in the PRIME ToC in detail and this may provide a starting point to develop a middle range theory to understand how to increase coverage of mental health services in low and middle income countries.

Although the focus of this work was to use ToC in the context of research, the lessons from this thesis are applicable to monitoring and evaluation professionals, NGOs, funders, policy makers and planners who could apply or use the ToC in their work. Further work is required

around the development of ToC in order to understand the perspectives of other stakeholders in the ToC process, and how to better incorporate complexity and context into the ToC. In addition, research is required to understand how one might further the use of mathematical modelling with ToC to predict the outcomes of health services interventions and understanding the role of ToC in the feasibility/piloting and implementation phases of the intervention.

Chapter 9. References

Adedokun, O. A., A. L. Childress and W. D. Burgess (2011). "Testing Conceptual Frameworks of Nonexperimental Program Evaluation Designs Using Structural Equation Modeling." American Journal of Evaluation **32**(4): 480-493.

Alkin, M. C. (2004). Evaluation roots : tracing theorists' views and influences. Thousand Oaks, California, Sage Publications.

Andersen, A. (2004). A Community Builder's Approach to Theory of Change: a Practical Guide to Theory Development. New York, The Aspen Insitute

Andersen, R., T. Nesman and S. Hodges (2012). Expressing Your Ideas: Using a Logic Model to Create System Change USF Logic Model Team, Tampa, Florida. Tools for Creating and Sustaining Human Services: Theory of Change Logic Models, University of South Florida

Anderson, R. (2008). "New MRC guidance on evaluating complex interventions." British Medical Journal **337**(7676): 944-945.

Andreas, D., D. Y. Ja and S. Wilson (2010). "Peers Reach Out Supporting Peers to Embrace Recovery (PROSPER): A Center for Substance Abuse Treatment Recovery Community Services Program." Alcoholism Treatment Quarterly **28**(3): 326-338.

Anselmi, L., P. Binyaruka and J. Borghi (2017). "Understanding causal pathways within health systems policy evaluation through mediation analysis: an application to payment for performance (P4P) in Tanzania." Implementation Science **12**(1): 10.

Asher, L. (2017). The development and evaluation of a community-based rehabilitation intervention for people with schizophrenia in Ethiopia. Doctor of Philosophy, London School of Hygiene & Tropical Medicine.

Asher, L., M. De Silva, C. Hanlon, H. A. Weiss, R. Birhane, D. A. Ejigu, G. Medhin, V. Patel and A. Fekadu (2016). "Community-based Rehabilitation Intervention for people with Schizophrenia in Ethiopia (RISE): study protocol for a cluster randomised controlled trial." Trials **17**(1): 299.

Asher, L., A. Fekadu, C. Hanlon, G. Mideksa, J. Eaton, V. Patel and M. J. De Silva (2015). "Development of a Community-Based Rehabilitation Intervention for People with Schizophrenia in Ethiopia." PLoS One **10**(11): e0143572.

Aspen Institute (1997). Voices from the field: Learning from the Early Work of Comprehensive Community Initiatives. Washington DC, Aspen Institute.

AusAID (2010). AUusAID's Mulitsectoral Contribution to the National Response in Papua New Guinea. Annex 10 Theory of Change.

Bacchus, L. J., S. Bewley, C. T. Vitolas, G. Aston, P. Jordan and S. F. Murray (2010). "Evaluation of a domestic violence intervention in the maternity and sexual health services of a UK hospital." Reproductive Health Matters **18**(36): 147-157.

Barnes, M., E. Matka and H. Sullivan (2003). "Evidence, Understanding and Complexity." Evaluation **9**(3): 265-284.

Barton, W. H., G. T. Powers, E. S. Morris and A. Harrison (2001). "Evaluating a comprehensive community initiative for children, youth, and families." Adolescent and Family Health **2**(1): 27-36.

Basson, H. A. and L. Roets (2013). "Workplace wellness for HIV/AIDS affected nurses in South Africa." British Journal of Nursing **22**(1): 38-44.

Bauer, G. F. (1999). Developing community health indicators to support comprehensive community building initiatives: A case study of a participatory action research project. Doctor of Public Health, University of California, Berkely.

Bauld, L., K. Judge, M. Barnes, M. Benzeval, M. MacKenzie and H. Sullivan (2005). "Promoting social change: The experience of health action zones in England." Journal of Social Policy **34**(3): 427-445.

Beeston, C., M. Robinson and N. Craig (2011). Monitoring and evaluating Scotland's alcohol strategy. Setting the Scene: theory of change and baseline picture. Edinburgh, NHS Health Scotland.

Benegal, V., P. K. Chand and I. S. Obot (2009). "Packages of care for alcohol use disorders in low-and middle-income countries." PLoS medicine **6**(10): e1000170.

Bhattacharjee, P. (2013). Use of Theory of Change to guide the design and monitoring of an intervention intended to reduce partner violence and increase protected sex among sex workers. STRIVE Annual Meeting. Karnataka

Birkby, B. W. (2001). The design and implementation of an evaluation for a comprehensive community-wide initiative on child maltreatment (Kentucky). Doctor of Psychology, Kentucky University.

Blamey, A. and M. Mackenzie (2007). "Theories of Change and Realistic Evaluation." Evaluation **13**(4): 439-455.

Bonner, L. (2003). "Using theory-based evaluation to build evidence-based health and social care policy and practice." Critical Public Health **13**(1): 77-92.

Brenman, N. F., N. P. Luitel, S. Mall and M. J. Jordans (2014). "Demand and access to mental health services: a qualitative formative study in Nepal." BMC International Health and Human Rights **14**: 22.

Breuer, E., M. De Silva, A. Fekadu, N. Luitel, V. Murhar, J. Nakku, I. Petersen and C. Lund (2014). "Using workshops to develop theories of change in five low and middle income countries: lessons from the programme for improving mental health care (PRIME)." International Journal of Mental Health Systems **8**(1): 15.

Breuer, E., M. J. De Silva, R. Shidaye, I. Petersen, J. Nakku, M. J. D. Jordans, A. Fekadu and C. Lund (2016). "Planning and evaluating mental health services in low- and middle-income countries using theory of change." British Journal of Psychiatry **208**(Suppl 56): s55-s62.

Breuer, E., L. Lee, M. De Silva and C. Lund (2016). "Using theory of change to design and evaluate public health interventions: a systematic review." Implementation Science **11**(1): 1.

Brown, E. C., J. D. Hawkins, I. C. Rhew, V. B. Shapiro, R. D. Abbott, S. Oesterle, M. W. Arthur, J. S. Briney and R. F. Catalano (2014). "Prevention System Mediation of Communities That Care Effects on Youth Outcomes." Prevention science : the official journal of the Society for Prevention Research **15**(5): 623-632.

Campbell, D. T. and J. C. Stanley (1963). Experimental and quasi-experimental designs for research. Chicago, Rand McNally.

Campbell, N. C., E. Murray and J. Darbyshire (2007). "Designing and evaluating complex interventions to improve health care." British Medical Journal **334**: 455-459.

Carr, S. M., M. Lhussier, J. Wilkinson and S. Gleadhill (2008). "Empowerment evaluation applied to public health practice." Critical Public Health **18**(2): 161-174.

Carroll, M., M. David, B. Jacobs, K. Judge and B. Wilkes (2005). "A realistic/theory of change approach to the evaluation of health promotion in small-and medium-sized enterprises in Sandwell." Social Policy and Society **4**(4): 393.

Centers for Disease Control and Prevention. Office of the Director, O. o. S. a. I., & National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases. (2006). Introduction to program evaluation for public health programs: Evaluating appropriate antibiotic use programs. Atlanta, GA, Centers for Disease Control and Prevention.

Central Bureau of Statistics (2014). National Poplulation and Housing Census 2011. Central Bureau of Statistics. Kathmandu, Nepal, National Planning Comission Secretariat, Government of Nepal.

Chandani, Y., M. Noel, A. Pomeroy, S. Andersson, M. K. Pahl and T. Williams (2012). "Factors Affecting Availability of Essential Medicines among Community Health Workers in Ethiopia, Malawi, and Rwanda: Solving the Last Mile Puzzle." American Journal of Tropical Medicine and Hygiene **87**(5): 120-126.

Chen, H. T. (1990). Theory Driven Evaluation. Thousand Oaks, California, Sage.

Chibanda, D., R. Verhey, E. Munetsi, F. M. Cowan and C. Lund (2016). "Using a theory driven approach to develop and evaluate a complex mental health intervention: the friendship bench project in Zimbabwe." International Journal of Mental Health Systems **10** (1): 16.

Chisholm, D. and S. Saxena (2012). "Cost effectiveness of strategies to combat neuropsychiatric conditions in sub-Saharan Africa and South East Asia: mathematical modelling study." British Medical Journal **344**: e609-e609. Chowdhary, N., A. Anand, S. Dimidjian, S. Shinde, B. Weobong, M. Balaji, S. D. Hollon, A. Rahman, G. T. Wilson, H. Verdeli, R. Araya, M. King, M. J. Jordans, C. Fairburn, B. Kirkwood and V. Patel (2015). "The Healthy Activity Program lay counsellor delivered treatment for severe depression

Chowdhary, N., A. Anand, S. Dimidjian, S. Shinde, B. Weobong, M. Balaji, S. D. Hollon, A. Rahman, G. T. Wilson, H. Verdeli, R. Araya, M. King, M. J. D. Jordans, C. Fairburn, B. Kirkwood and V. Patel (2016). "The Healthy Activity Program lay counsellor delivered treatment for severe depression in India: systematic development and randomised evaluation." The British Journal of Psychiatry **208**(4): 381-388.

Clarke, D. J., M. Godfrey, R. Hawkins, E. Sadler, G. Harding, A. Forster, C. McKevitt, J. Dickerson and A. Farrin (2013). "Implementing a training intervention to support caregivers after stroke: A process evaluation examining the initiation and embedding of programme change." Implementation Science **8**(1): 96-96.

Cohen, A., J. Eaton, B. Radtke, C. George, B. V. Manuel, M. De Silva and V. Patel (2011). "Three models of community mental health services In low-income countries." International Journal of Mental Health Systems **5**: 3-3.

Cole, D. C., S. Hogg-Johnson, M. Manno, S. Ibrahim, R. P. Wells, S. E. Ferrier and G. Worksite Upper Extremity Research (2006). "Reducing musculoskeletal burden through ergonomic program implementation in a large newspaper." International Archives of Occupational and Environmental Health **80**(2): 98-108.

Cole, M. (2003). "The health action zone initiative: Lessons from Plymouth." Local Government Studies **29**(3): 99-117.

Collins, P. Y., T. R. Insel, A. Chockalingam, A. Daar and Y. T. Maddox (2013). "Grand Challenges in Global Mental Health: Integration in Research, Policy, and Practice." PLoS Medicine **10**(4): e1001434.

Connell, J. P. and A. C. Kubisch (1998). Applying a Theory of Change Approach to the Evaluation of Comprehensive Community Initiatives: Progress, Prospects, and Problems. New Approaches to Evaluating Community Initiatives, Vol. 2: Theory, Measurement, and Analysis K. Fulbright-Andersen, A. Kubisch and J. P. Connell. United States of America, The Aspen Institute**:** 15-44.

Coryn, C. L. S., L. a. Noakes, C. D. Westine and D. C. Schroter (2010). "A Systematic Review of Theory-Driven Evaluation Practice From 1990 to 2009." American Journal of Evaluation **32**: 199-226.

Craig, P., P. Dieppe, S. Macintyre, S. Michie, I. Nazareth and M. Petticrew (2012). "Developing and evaluating complex interventions: The new Medical Research Council guidance." International Journal of Nursing Studies **50**: 587-592.

Craig, P., P. Dieppe, S. Macintyre, S. Michie, I. Nazareth, M. Petticrew and G. Medical Research Council (2008). "Developing and evaluating complex interventions: the new Medical Research Council guidance." British Medical Journal **337**: a1655.

Crosby, R. and S. M. Noar (2011). "What is a planning model? An introduction to PRECEDE-PROCEED." Journal of Public Health Dentistry **71 Suppl 1**: S7-15.

Dabholkar, H., A. Nadkarni, R. Velleman and V. Patel (2014). Counselling for Alcohol Problems (CAP). Goa, Sangath.

Davies, R. (2017). "Rick on the Road." Retrieved 2018, 26th January, from http://mandenews.blogspot.co.za/.

de Jesus Mari, J., D. Razzouk, R. Thara, J. Eaton and G. Thornicroft (2009). "Packages of care for schizophrenia in low-and middle-income countries." PLoS medicine **6**(10): e1000165.

De La Rosa, I. A., J. Perry, L. E. Dalton and V. Johnson (2005). "Strengthening families with first-born children: Exploratory story of the outcomes of a home visiting intervention." Research on Social Work Practice **15**(5): 323-338.

De La Rosa, I. A., J. Perry and V. Johnson (2009). "Benefits of increased home-visitation services: Exploring a case management model." Family and Community Health **32**(1): 58-75.

De Silva, M. J., E. Breuer, L. Lee, L. Asher, N. Chowdhary, C. Lund and V. Patel (2014). "Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions." Trials **15**(1): 267.

De Silva, M. J., S. D. Rathod, C. Hanlon, E. Breuer, D. Chisholm, A. Fekadu, M. Jordans, F. Kigozi, I. Petersen, R. Shidhaye, G. Medhin, J. Ssebunnya, M. Prince, G. Thornicroft, M. Tomlinson, C. Lund and V. Patel (2016). "Evaluation of district mental healthcare plans: the PRIME consortium methodology." British Journal of Psychiatry.

De Silva, M. J., L. Lee, D. C. Fuhr, S. Rathod, D. Chisholm, J. Schellenberg and V. Patel (2014). "Estimating the coverage of mental health programmes: a systematic review." Int J Epidemiol **43**(2): 341-353.

Demyttenaere, K., R. Bruffaerts, J. Posada-Villa, I. Gasquet, V. Kovess, J. P. Lepine, M. C. Angermeyer, S. Bernert, G. de Girolamo, P. Morosini, G. Polidori, T. Kikkawa, N. Kawakami, Y. Ono, T. Takeshima, H. Uda, E. G. Karam, J. A. Fayyad, A. N. Karam, Z. N. Mneimneh, M. E. Medina-Mora, G. Borges, C. Lara, R. de Graaf, J. Ormel, O. Gureje, Y. Shen, Y. Huang, M. Zhang, J. Alonso, J. M. Haro, G. Vilagut, E. J. Bromet, S. Gluzman, C. Webb, R. C. Kessler, K. R. Merikangas, J. C. Anthony, M. R. Von Korff, P. S. Wang, T. S. Brugha, S. Aguilar-Gaxiola, S. Lee, S. Heeringa, B. E. Pennell, A. M. Zaslavsky, T. B. Ustun, S. Chatterji and WHO World Mental Health Survey Consortium (2004). "Prevalence, severity, and unmet need for treatment of mental disorders in the World Health Organization World Mental Health Surveys." The Journal of the American Medical Association **291**(21): 2581-2590.

Dieppe, P. (2006). MRC Complex Intervention Workshop Report. Workshop report for the PHSRN and HSPHRB. UK, Medical Research Council.

Dill, J. S., E. Chuang and J. C. Morgan (2014). "Healthcare organization-education partnerships and career ladder programs for health care workers." Social Science and Medicine **122**: 63-71.

Dixon-Woods, M., C. L. Bosk, E. L. Aveling, C. A. Goeschel and P. J. Pronovost (2011). "Explaining Michigan: developing an ex post theory of a quality improvement program." Milbank Quarterly **89**(2): 167-205.

Dixon-Woods, M., C. Tarrant, J. Willars and A. Suokas (2010). "How will it work? A qualitative study of strategic stakeholders' accounts of a patient safety initiative." Quality and Safety in Health Care **19**(1): 74-78.

Donabedian, A., J. R. Wheeler and L. Wyszewianski (1982). "Quality, cost, and health: an integrative model." Medical care: 975-992.

Dua, T., C. Barbui, N. Clark, A. Fleischmann, V. Poznyak, M. van Ommeren, M. T. Yasamy, J. L. Ayuso-Mateos, G. L. Birbeck, C. Drummond, M. Freeman, P. Giannakopoulos, I. Levav, I. S. Obot, O. Omigbodun, V. Patel, M. Phillips, M. Prince, A. Rahimi-Movaghar, A. Rahman, J. W. Sander, J. B. Saunders, C. Servili, T. Rangaswamy, J. Unutzer, P. Ventevogel, L. Vijayakumar, G. Thornicroft and S. Saxena (2011). "Evidence-based guidelines for mental, neurological, and substance use disorders in low- and middle-income countries: summary of WHO recommendations." PLoS Medicine **8**(11): e1001122.

Ekirapa-Kiracho, E., U. Ghosh, R. Brahmachari and L. Paina (2017). "Engaging stakeholders: lessons from the use of participatory tools for improving maternal and child care health services." Health Research in Policy and Systems **15**(Suppl 2): 106.

Endnote (2015). Endnote. San Fransisco, Thomson Reuters.

Evernote Cooperation (2015). Evernote.

Farquhar, M. C., G. Ewing and S. Booth (2011). "Using mixed methods to develop and evaluate complex interventions in palliative care research." Palliative medicine **25**: 748-757.

Fekadu, A., C. Hanlon, G. Medhin, A. Alem, M. Selamu, T. W. Giorgis, T. Shibre, S. Teferra, T. Tegegn and E. Breuer (2016). "Development of a scalable mental healthcare plan for a rural district in Ethiopia." The British Journal of Psychiatry **208 Suppl 56**: s4-12.

Fetterman, D. M., S. J. Kaftarian and A. Wandersman (1996). Empowerment evaluation: Knowledge and tools for self-assessment and accountability, Sage.

Funnell, S. C. and P. J. Rogers (2011). Purposeful program theory : effective use of theories of change and logic models. San Francisco, CA, Jossey-Bass.

Garson, D. (2016). Case Study Analysis and QCA. Asheboro, North Carolina, Statistical Associates Publishing.

Gilson, L. (2012). Health systems and institutions. Health systems in low- and middle-income countries : an economic and policy perspective. R. J. Smith and K. Hanson. Oxford, Oxford University Press.

Glasgow, R. E. and P. E. Estabrooks (2018). "Pragmatic Applications of RE-AIM for Health Care Initiatives in Community and Clinical Settings." Prev Chronic Dis **15**: E02.

Glouberman, S. and B. Zimmerman (2002). Complicated and Complex Systems : What Would Successful Reform of Medicare Look Like ? . Discussion Paper No. 8, Comission on the Future of Health Care in Canada.

Goicolea, I., C. Vives-Cases, A. K. Hurtig, B. Marchal, E. Briones-Vozmediano, L. Otero-Garcia, M. Garcia-Quinto and M. San Sebastian (2015). "Mechanisms that Trigger a Good Health-Care Response to Intimate Partner Violence in Spain. Combining Realist Evaluation and Qualitative Comparative Analysis Approaches." PLoS One **10**(8): e0135167.

Goncalves, D. A., S. Fortes, M. Campos, D. Ballester, F. B. Portugal, L. F. Tófoli, L. Gask, J. Mari and P. Bower (2013). "Evaluation of a mental health training intervention for multidisciplinary teams in primary care in Brazil: a pre-and posttest study." General hospital psychiatry **35**(3): 304-308.

Goss-Power, P. J. (2005). Evaluation of a school-based program for youth with emotional and behavioral disabilities. Doctor of Psychology, Antioch New England Graduate School.

Granger, R. C. (1998). Establishing Causalty in Evaluations of Comprehensive Community Initiatives. New Approaches to Evaluating Community Initiatives, Vol. 2: Theory, Measurement, and Analysis. J. P. Connell, A. C. Kubisch and K. Fulbright-Andersen. New York, The Aspen Insitutute.

Gray, P. and T. Seddon (2005). "Prevention work with children disaffected from school: Findings from the evaluation of two innovative community-based projects." Health Education **105**(1): 62-72.

Green, L. and M. Kreuter (1999). "The precede–proceed model." Health promotion planning: an educational approach. 3rd ed. Mountain View (CA): Mayfield Publishing Company: 32-43.

Greenhalgh, T., G. Robert, F. Macfarlane, P. Bate and O. Kyriakidou (2004). "Diffusion of innovations in service organizations: Systematic review and recommendations." Milbank Q **82**(4): 581 - 629.

Gregor, M. (2009) "TB Alert Change Story Map."

Guba, E. G. and Y. S. Lincoln (1989). Fourth generation evaluation, Sage.

Hailemariam, M., A. Fekadu, M. Selamu, A. Alem, G. Medhin, T. W. Giorgis, M. DeSilva and E. Breuer (2015). "Developing a mental health care plan in a low resource setting: the theory of change approach." BMC Health Services Research **15**: 429.

Hanlon, C., A. Fekadu, M. Jordans, F. Kigozi, I. Petersen, R. Shidhaye, S. Honikman, C. Lund, M. Prince and S. Raja (2016). "District mental healthcare plans for five low-and middle-income countries: commonalities, variations and evidence gaps." The British Journal of Psychiatry: bjp. bp. 114.153767.

Hanlon, C., N. P. Luitel, T. Kathree, V. Murhar, S. Shrivasta, G. Medhin, J. Ssebunnya, A. Fekadu, R. Shidhaye, I. Petersen, M. Jordans, F. Kigozi, G. Thornicroft, V. Patel, M. Tomlinson, C. Lund, E. Breuer, M. De Silva and M. Prince (2014). "Challenges and opportunities for implementing integrated mental health care: a district level situation analysis from five low- and middle-income countries." PLoS One **9**(2): e88437.

Hawe, P. (2015). "Lessons from Complex Interventions to Improve Health." Annual Review of Public Health **36**(1): 307-323.

Hawe, P. (2015). "Minimal, negligible and negligent interventions." Social Science and Medicine **138**: 265-268.

Hawe, P., A. Shiell and T. Riley (2004). "Complex interventions: how 'out of control' can a randomised controlled trial be?" British Medical Journal **328**(7455): 1561-1563.

Hawe, P., A. Shiell, T. Riley and L. Gold (2004). "Methods for exploring implementation variation and local context within a cluster randomised community intervention trial." Journal of Epidemiology and Community Health **58**(9): 788-793.

Henderson, C., J. Noblett, H. Parke, S. Clement, A. Caffrey, O. Gale-Grant, B. Schulze, B. Druss and G. Thornicroft (2014). "Mental health-related stigma in health care and mental health-care settings." The Lancet Psychiatry **1**(6): 467-482.

Henderson, P. M. (2004). Program evaluation of a long-term substance abuse treatment program for homeless men. Doctor of Psychology, Spalding University.

Hernandez, M. and S. Hodges (2006). "Applying a theory of change approach to interagency planning in child mental health." American Journal of Community Pscyhology **38**(3-4): 165-173.

Hino, A. (2009). "Time-Series QCA." 理論と方法 (Sociological Theory and Methods) **24**(2): 247-265.

Hunter, D. E. K. (2006). "Using a theory of change approach to build organizational strength , capacity and sustainability with not-for-profit organizations in the human services sector *." Evaluation and Program Planning **29**: 193-200.

Illinois Caucus for Adolescent Health. (2013). "Strategic Plan." Retrieved 16th January 2014, from http://www.icah.org/content/strategic-plan.

Irvine, J. F. (1979). "Goal-free evaluation: Philosophical and ethical aspects of Michael Scriven's model." California Journal of Teacher Education: 89-99.

Israel, B. A., A. J. Schulz, E. A. Parker and A. B. Becker (1998). "Review of community based research: Assessing Partnership Approaches to Improve Public Health." Annual Review of Public Health **19**(1): 173-202.

James, C. (2011). Theory of Change Review. A report commissioned by Comic Relief. London, Comic Relief.

James, C. (2013) "Theory of Change: A Guide for Small and Diaspora NGOs." London, The Peer Learning Programme for Small and Diaspora Organisations.

Jenkins, R., C. Othieno, S. Okeyo, D. Kaseje, J. Aruwa, H. Oyugi, P. Bassett and F. Kauye (2013). "Short structured general mental health in service training programme in Kenya improves patient health and social outcomes but not detection of mental health problems-a pragmatic cluster randomised controlled trial." International Journal of Mental Health Systems **7**(1): 25.

Jordans, M. J., N. P. Luitel, P. Pokhrel and V. Patel (2016). "Development and pilot testing of a mental healthcare plan in Nepal." British Journal of Psychiatry **208 Suppl 56**: s21-28.

Jordans, M. J., B. A. Kohrt, N. P. Luitel, I. H. Komproe and C. Lund (2015). "Accuracy of proactive case finding for mental disorders by community informants in Nepal." British Journal of Psychiatry **207**(6): 501-506.

Jordans, M. J., B. A. Kohrt, N. P. Luitel, C. Lund and I. H. Komproe (2017). "Proactive community case-finding to facilitate treatment seeking for mental disorders, Nepal." Bulletin of the World Health Organisation **95**(7): 531-536.

Jordans, M. J., N. P. Luitel, M. Tomlinson and I. H. Komproe (2013). "Setting priorities for mental health care in Nepal: a formative study." BMC Psychiatry **13**: 332.

Kakuma, R., H. Minas, N. van Ginneken, M. R. Dal Poz, K. Desiraju, J. E. Morris, S. Saxena and R. M. Scheffler (2011). "Human resources for mental health care: current situation and strategies for action." Lancet **378**(9803): 1654-1663.

Kane, H., L. Hinnant, K. Day, M. Council, J. Tzeng, R. Soler, M. Chambard, A. Roussel and W. Heirendt (2017). "Pathways to Program Success: A Qualitative Comparative Analysis (QCA) of Communities Putting Prevention to Work Case Study Programs." Journal of Public Health Management and Practice **23**(2): 104-111.

Kane, H., M. A. Lewis, P. A. Williams and L. C. Kahwati (2014). "Using qualitative comparative analysis to understand and quantify translation and implementation." Tranlational Behavioural Medicine **4**(2): 201-208.

Kane, J. C., N. P. Luitel, M. J. Jordans, B. A. Kohrt, I. Weissbecker and W. A. Tol (2017). "Mental health and psychosocial problems in the aftermath of the Nepal earthquakes: findings from a representative cluster sample survey." Epidemiolgy and Psychiatric Services: 1-10 doi:10.1017/S2045796016001104.

Kauye, F., R. Jenkins and A. Rahman (2014). "Training primary health care workers in mental health and its impact on diagnoses of common mental disorders in primary care of a developing country, Malawi: a cluster-randomized controlled trial." Psychological Medicine **44**(3): 657-666.

Kemp, L., E. Harris, C. McMahon, S. Matthey, G. Vimpani, T. Anderson, V. Schmied and H. Aslam (2013). "Benefits of psychosocial intervention and continuity of care by child and family health nurses in the pre- and postnatal period: process evaluation." Journal of Advanced Nursing **69**(8): 1850-1861.

Kigozi, F. N., D. Kizza, J. Nakku, J. Ssebunnya, S. Ndyanabangi, B. Nakiganda, C. Lund and V. Patel (2016). "Development of a district mental healthcare plan in Uganda." British Journal of Psychiatry **208 Suppl 56**: s40-46.

King, J. A. (2005). Participatory evaluation. Encyclopedia of evaluation**:** 291-294.

Kleinman, A. (2004). "Culture and depression." New England Journal of Medicine **351**(10): 951-953.

Kleintjes, S., C. Lund, L. Swartz, A. Flisher and C. The Mhapp Research Programme (2010). "Mental health care user participation in mental health policy development and implementation in South Africa." International Review of Psychiatry **22**(6): 568-577.

Knowlton, L. W. and C. Phillips (2012). "Corporate Giving Gets Smarter: ConAgra Foods Foundation Fights Childhood Hunger." Foundation Review **4:2**: doi: 10,4087/FOUNDATiONREVIEW-D-4011-00034.00031.

Kreger, M., K. Sargent, A. Arons, M. Standish and C. D. Brindis (2011). "Creating an environmental justice framework for policy change in childhood asthma: a grassroots to treetops approach." American Journal of Public Health **101 Suppl 1**: S208-216.

Lagarde, M. (2012). "How to do (or not to do) ... Assessing the impact of a policy change with routine longitudinal data." Health Policy And Planning **27**(1): 76-83.

Lee, L. (2014). "Using Theory of Change? You need a champion." Retrieved 13th Feburary, 2017, from http://www.mhinnovation.net/blog/2014/jun/11/using-theory-change-you-need-champion#.VcSeL_NVhBc.

Lehmann, U. and L. Gilson (2013). "Actor interfaces and practices of power in a community health worker programme: a South African study of unintended policy outcomes." Health Policy And Planning **28**(4): 358-366.

Levinson-Johnson, J. (2012). Monroe Country ACCESS Logic Model. Tools for Creating and Sustaining Human Services: Theory of Change Logic Models, University of South Florida

Levison-Johnson, J. and M. Wenz-Gross (2010). "From complexity to reality: providing useful frameworks for defining systems of care." Evaluation and Program Planning **33**(1): 56-58.

Levesque, J.-F., M. F. Harris and G. Russell (2013). "Patient-centred access to health care: conceptualising access at the interface of health systems and populations." International Journal for Equity in Health 12(1): 18.

Lewin, S., C. Glenton and a. D. Oxman (2009). "Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study." British Medical Journal **339**: b3496-b3496.

Li, J., J. Li, G. Thornicroft and Y. Huang (2014). "Levels of stigma among community mental health staff in Guangzhou, China." BMC Psychiatry **14**: 231.

Ling, T. (2012). "Evaluating complex and unfolding interventions in real time." Evaluation **18**: 79-91.

Linnan, L. and A. Steckler (2002). Process Evaluation for Public Health Interventions and Research: an overview. Process Evaluation for Public Health Interventions and Research. A. Steckler and L. Linnan. San Fransisco, Josey-Bass**:** 1-24.

Longest, K. C. and S. Vaisey (2008). "fuzzy: A program for performing qualitative comparative analyses (QCA) in " Stata Journal **8**(1): 79.

Luitel, N. P., M. J. Jordans, A. Adhikari, N. Upadhaya, C. Hanlon, C. Lund and I. H. Komproe (2015). "Mental health care in Nepal: current situation and challenges for development of a district mental health care plan." Conflict and Health **9**: 3.

Luitel, N. P., M. J. D. Jordans, B. A. Kohrt, S. D. Rathod and I. H. Komproe (2017). "Treatment gap and barriers for mental health care: A cross-sectional community survey in Nepal." PLoS One **12**(8): e0183223.

Lund, C., M. Tomlinson, M. De Silva, A. Fekadu, R. Shidaye, M. J. D. Jordans, I. Petersen, F. Kigozi, M. Prince, G. Thornicroft, C. Hanlon, R. Kakuma, D. McDaid, S. Saxena, D. Chisholm, S. Raja, S. Kippen-Wood, S. Honikman, L. Fairall and V. Patel (2012). "PRIME: a programme to reduce the treatment gap for mental disorders in five low- and middle-income countries." PLoS Med **9**(12): e1001359.

Macfarlane, F., T. Greenhalgh, C. Humphrey, J. Hughes, C. Butler and R. Pawson (2011). "A new workforce in the making?: A case study of strategic human resource management in a whole-system change effort in healthcare." Journal of Health, Organisation and Management **25**(1): 55-72.

Mackenzie, M. (2006). "Benefit or burden: introducing paraprofessional support staff to health visiting teams: the case of Starting Well." Health and Social Care in the Community **14**(6): 523-531.

Mackenzie, M. (2008). "Evaluating complex interventions : one size does not fit all." BMC Health Services Research **340:c185.**: 401-403.

Mackenzie, M. and A. Blamey (2005). "The practice and the theory: Lessons from the application of a theories of change approach." Evaluation **11**(2): 151-168+245.

Mackenzie, M., A. Blamey, E. Halliday, M. Maxwell, A. McCollam, D. McDaid, J. MacLean, A. Woodhouse and S. Platt (2007). "Measuring the tail of the dog that doesn't bark in the night: The case of the national evaluation of Choose Life (the national strategy and action plan to prevent suicide in Scotland)." BMC Public Health **7**.

Mackenzie, M., C. O'Donnell, E. Halliday, S. Sridharan and S. Platt (2010). "Do health improvement programmes fit with MRC guidance on evaluating complex interventions?" British Medical Journal **340**: c185.

Mackenzie, M., M. Reid, F. Turner, Y. Y. Wang, J. Clarke, S. Sridharan, S. Platt and C. O'Donnell (2012). "Reaching the Hard-to-Reach: Conceptual Puzzles and Challenges for Policy and Practice." Journal of Social Policy **41**(03): 511-532.

Maglio, P. P. and P. L. Mabry (2011). "Agent-Based Models and Systems Science Approaches to Public Health." American Journal of Preventive Medicine **40**(3): 392-394.

Marchal, B., S. van Belle, J. van Olmen, T. Hoeree and G. Kegels (2012). "Is realist evaluation keeping its promise? A review of published empirical studies in the field of health systems research." Evaluation **18**: 192-212.

Maselli, B. (2012). Thrive Community Youth Logic Model: Working Together for a Brighter Tomorrow Lewiston, Maine. Tools for Creating and Sustaining Human Services: Theory of Change Logic Models, University of South Florida

Mason, P. (2005). "Visual data in applied qualitative research: Lessons from experience." Qualitative Research **5**(3): 325-346.

Mason, P. and M. Barnes (2007). "Constructing theories of change: Methods and sources." Evaluation **13**(2): 151-170.

May, C. (2013). "Towards a general theory of implementation." Implementation Science **8**(1): 18.

May, C., F. Mair, T. Finch, A. MacFarlane, C. Dowrick, S. Treweek, T. Rapley, L. Ballini, B. Ong and A. Rogers (2009). "Development of a theory of implementation and integration: Normalization Process Theory." Implement Sci **4**: 29.

Mays, N. and C. Pope (2000). "Assessing quality in qualitative research." British Medical Journal **320**(7226): 50-52.

McAlearney, A. S., D. Walker, A. D. Moss and N. A. Bickell (2016). "Using Qualitative Comparative Analysis of Key Informant Interviews in Health Services Research: Enhancing a Study of Adjuvant Therapy Use in Breast Cancer Care." Medical Care **54**(4): 400-405.

McIntyre, D., M. Thiede and S. Birch (2009). "Access as a policy-relevant concept in low- and middle-income countries." Health Econ Policy Law 4(Pt 2): 179-193

McQuiston, C., S. Choi-Hevel and M. Clawson (2001). "Protegiendo nuestra comunidad: Empowerment participatory education for HIV prevention." Journal of Transcultural Nursing **12**(4): 275-283.

Medical Research Council (2000). A framework for the development and evaluation of RCTs for complex interventions to improve health. UK, Medical Research Council.

Medical Research Council (2008). Developing and evaluating complex interventions: new guidance. United Kingdom, Medical Research Council.

Mental Health Innovation Network. (2014). "Theory of Change Toolkit." Retrieved 26th January 2018, from http://www.mhinnovation.net/resources/theory-change-toolkit.

Moher, D., A. Liberati, J. Tetzlaff and D. G. Altman (2009). "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement." PLoS Medicine **6**: e1000097.

Möhler, R., S. Köpke and G. Meyer (2015). "Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2)." Trials **16**(1): 204.

Mookherji, S. and A. LaFond (2013). "Strategies to maximize generalization from multiple case studies: Lessons from the Africa Routine Immunization System Essentials (ARISE) project." Evaluation **19**(3): 284-303.

Moore, G. F., S. Audrey, M. Barker, L. Bond, C. Bonell, W. Hardeman, L. Moore, A. O'Cathain, T. Tinati, D. Wight and J. Baird (2015). Process evaluation of complex interventions, UK Medical Research Council Guidance.

Moore, G. F., S. Audrey, M. Barker, L. Bond, C. Bonell, W. Hardeman, L. Moore, A. O'Cathain, T. Tinati, D. Wight and J. Baird (2015). "Process evaluation of complex interventions: Medical Research Council guidance." British Medical Journal **350**.

Moore, G. F. and R. E. Evans (2017). "What theory, for whom and in which context? Reflections on the application of theory in the development and evaluation of complex population health interventions." SSM - Population Health **3**: 132-135.

Morilus-Black, M., V. McCarthy and J. B. Kernan (2012). Using a Logic Model as a Tool to Apply a Theory of Change Approach to Support Implementation, Evaluation and Strategic Planning. Tools for Creating and Sustaining Human Services: Theory of Change Logic Models, University of South Florida

MRC (2000). A framework for the development and evaluation of RCTs for complex interventions to improve health. UK, Medical Research Council.

Murray, E., S. Treweek, C. Pope, A. MacFarlane, L. Ballini, C. Dowrick, T. Finch, A. Kennedy, F. Mair, C. O. Donnell, B. N. Ong, T. Rapley, A. Rogers, C. O'Donnell, B. N. Ong, T. Rapley, A. Rogers and C. May (2010). "Normalisation process theory: a framework for developing, evaluating and implementing complex interventions." BMC Medicine **8**: 63.

Nilsen, P. (2015). "Making sense of implementation theories, models and frameworks." Implementation Science **10**(1): 53.

Novella, E. J. (2010). "Mental Health Care in the Aftermath of Deinstitutionalization: A Retrospective and Prospective View." Health Care Analysis **18**(3): 222-238.

Oakley, A., V. Strange, C. Bonell, E. Allen and J. Stephenson (2006). "Process evaluation in randomised controlled trials of complex interventions." British Medical Journal **332**: 413-416.

Paina, L., A. Wilkinson, M. Tetui, E. Ekirapa-Kiracho, D. Barman, T. Ahmed, S. S. Mahmood, G. Bloom, J. Knezovich and A. George (2017). "Using Theories of Change to inform implementation of health systems research and innovation: experiences of Future Health Systems consortium partners in Bangladesh, India and Uganda." Health research policy and systems **15**(2): 109.

Painuly, N. and P. Sharan (2008). "Effectiveness of training of non-mental health care providers in mental health in low-and middle-income countries: a systematic review." Primary Care and Community Psychiatry **13**(2): 83-89.

Patel, V., G. S. Belkin, A. Chockalingam, J. Cooper, S. Saxena and J. Unützer (2013). "Grand Challenges: Integrating Mental Health Services into Priority Health Care Platforms." PLoS Medicine **10**(5): e1001448.

Patel , V. and M. Prince (2010). "Global Mental Health: a new global health field comes of age." Journal of the American Medical Association **303**: 1976-1977.

Patel, V., G. Simon, N. Chowdhary, S. Kaaya and R. Araya (2009). "Packages of care for depression in low-and middle-income countries." PLoS medicine **6**(10): e1000159.

Patel, V. and G. Thornicroft (2009). "Packages of care for mental, neurological, and substance use disorders in low- and middle-income countries: PLoS Medicine Series." PLoS Medicine **6**(10): e1000160.

Patton, M. Q. (2008). Utilization-focused evaluation, Saint Paul, Sage publications.

Pawson, R. (2003). "Nothing as Practical as a Good Theory." Evaluation **9**: 471.

Pawson, R. and N. Tilley (1997). Realistic evaluation. London ; Thousand Oaks, California, Sage.

Pelican Initiative. (2018). "Pelican Initiative: Platform for Evidence-based Learning & Communication for Social Change " Retrieved 2018, 26th January, from https://dgroups.org/groups/pelican.

Peters, D. H. (2014). "The application of systems thinking in health: why use systems thinking?" Health Research Policy and Systems **12**(1): 51.

Petersen, I., L. Fairall, A. Bhana, T. Kathree, O. Selohilwe, C. Brooke-Sumner, G. Faris, E. Breuer, N. Sibanyoni, C. Lund and V. Patel (2016). "Integrating mental health into chronic

care in South Africa: the development of a district mental healthcare plan." British Journal of Psychiatry **208 Suppl 56**: s29-39.

Plsek, P. E. and T. Greenhalgh (2001). "Complexity science: The challenge of complexity in health care." British Medical Journal **323**(7313): 625-628.

Prinsen, G. and S. Nijhof (2015). "Between logframes and theory of change: reviewing debates and a practical experience." Development in Practice **25**(2): 234-246.

Proctor, E. K., J. Landsverk, G. Aarons, D. Chambers, C. Glisson and B. Mittman (2009). "Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges." Adminitration and Policy in Mental Health and Services **36**(1): 24-34.

Provus, M. (1971). Discrepancy evaluation. Berkeley, McCutchan.

QRS (2011). NVIVO. Victoria, QRS.

Ragin, C. (2008). Fuzzy set analysis: Calibration vs. Measurement. The Oxford handbook of political methodology. J. M. Box-Steffensmeier, H. E. Brady and D. Collier. Oxford, Oxford University Press**.**

Ragin, C. and S. Davey (2014). fs/QCA. Irvine, CA, University of California.

Ragin, C. C. (1999). "Using qualitative comparative analysis to study causal complexity." Health Services Research **34**(5 Pt 2): 1225-1239.

Rathod, S. D., M. J. De Silva, J. Ssebunnya, E. Breuer, V. Murhar, N. P. Luitel, G. Medhin, F. Kigozi, R. Shidhaye, A. Fekadu, M. Jordans, V. Patel, M. Tomlinson and C. Lund (2016). "Treatment contact coverage for probable depressive and probable alcohol use disorders in four low- and middle-income country districts: The prime cross-sectional community surveys." PLoS One **11**(9).

Reid, M. and Y. Botma (2012). "A framework to expand public services to children with biomedical healthcare needs related to HIV in the Free State, South Africa." African Journal of Aids Research **11**(2): 91-98.

Research Councils UK. (2018). "Identifying and critiquing different approaches to developing complex interventions (INDEX study)." Retrieved 25th January, 2018.

Research Councils UK. (2018). " Strengthening responses to dementia in developing countries." Retrieved 25th January, 2018, from http://gtr.rcuk.ac.uk/projects?ref=ES%2FP010938%2F1.

Rihoux, B. and C. C. Ragin (2008). Configurational comparative methods: Qualitative comparative analysis (QCA) and related techniques, Sage Publications.

Riley, A. J., R. Byng, C. White and S. Smith (2008). "Utilising theories of change to understand the engagement of general practitioners in service improvement: A formative evaluation of the Lewisham Depression Programme." Quality in Primary Care **16**(1): 17-26.

Ritchie, J. and L. Spencer (1994). Qualitative data analysis for applied policy research. Analysing qualitative data. Bryman and Burgess. London, Routledge**:** 173-194.

Rivera, J. A., R. Martorell, W. Gonzalez, C. Lutter, T. G. Cossio, R. Flores-Ayala, R. Uauy, H. Delgado and S. M. S. Grupo Tecnico de Nutricion del (2011). "Prevención de la desnutrición de la madre y el niño: el componente de nutrición de la Iniciativa Salud Mesoamérica 2015." Salud Pública de México **53 Suppl 3**: S303-311.

Rodriguez, M. H., A. F. Betanzos-Reyes and P. Grupo de Trabajo de Malaria del Sistema Mesoamericano de Salud (2011). "Plan de mejoramiento del control de la malaria hacia su eliminación en Mesoamérica." Salud Pública de México **53 Suppl 3**: S333-348.

Rogers, P. (2008). "Using programme theory to evaluate complicated and complex aspects of interventions." Evaluation **14**: 29-48.

Rossi, P. H. and H. E. Freeman (1985). Evaluation: A systematic approach, Sage publications.

Rutter, H., N. Savona, K. Glonti, J. Bibby, S. Cummins, D. T. Finegood, F. Greaves, L. Harper, P. Hawe and L. Moore (2017). "The need for a complex systems model of evidence for public health." The Lancet **390**(10112): 2602-2604.

Rychetnik, L., M. Frommer, P. Hawe and A. Shiell (2002). "Criteria for evaluating evidence on public health interventions." Journal of Epidemiology and Community Health **56**: 119-127.

Sackett, D. L., W. M. C. Rosenberg, J. A. M. Gray, R. B. Haynes and W. S. Richardson (1996). "Evidence based medicine: what it is and what it isn't." BMJ **312**(7023): 71-72.

Saraceno, B., M. Van Ommeren, R. Batniji, A. Cohen, O. Gureje, J. Mahoney, D. Sridhar and C. Underhill (2007). "Barriers to improvement of mental health services in low-income and middle-income countries." The Lancet **370**(9593): 1164-1174.

Saxena, S., M. Funk and D. Chisholm (2013). "World Health Assembly adopts Comprehensive Mental Health Action Plan 2013—2020." The Lancet **381**(9882): 1970-1971.

Saxena, S., G. Thornicroft, M. Knapp and H. Whiteford (2007). "Resources for mental health: scarcity, inequity, and inefficiency." The Lancet **370**(9590): 878-889.

Scanlon, D. P., J. Beich, J. A. Alexander, J. B. Christianson, R. Hasnain-Wynia, M. C. McHugh and J. N. Mittler (2012). "The Aligning Forces for Quality Initiative: Background and Evolution From 2005 to 2012." American Journal of Managed Care **18**: S115-125.

Schierhout, G., J. Hains, D. Si, C. Kennedy, R. Cox, R. Kwedza, L. O'Donoghue, M. Fittock, J. Brands, K. Lonergan, M. Dowden and R. Bailie (2013). "Evaluating the effectiveness of a multifaceted, multilevel continuous quality improvement program in primary health care: Developing a realist theory of change." Implementation Science **8**(1).

Schulz, K. F., D. G. Altman and D. Moher (2010). "CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials." BMC Medicine **8**(1): 18.

Secker, J., H. Bowers, D. Webb and M. Llanes (2005). "Theories of change: what works in improving health in mid-life?" Health education research **20**(4): 392-401.

Sehon, S. R. and D. E. Stanley (2003). "A philosophical analysis of the evidence-based medicine debate." BMC Health Services Research **3**: 14-14.

Shearn, K., P. Allmark, H. Piercy and J. Hirst (2017). "Building Realist Program Theory for Large Complex and Messy Interventions." International Journal of Qualitative Methods **16**(1): 1609406917741796.

Sheehy, T. J. and N. M. Thygeson (2014). "Physician organization care management capabilities associated with effective inpatient utilization management: a fuzzy set qualitative comparative analysis." BMC Health Services Research **14**: 582.

Sheikh, K. and J. D. Porter (2011). "Disempowered doctors? A relational view of public health policy implementation in urban India." Health Policy And Planning **26**(1): 83-92.

Shepperd, S., S. Lewin, S. Straus, M. Clarke, M. P. Eccles, R. Fitzpatrick, G. Wong and A. Sheikh (2009). "Can we systematically review studies that evaluate complex interventions?" PLoS Medicine **6**(8): e1000086.

Shidhaye, R. (2015). "Implementation Science for closing the treatment gap for mental disorders by translating evidence base into practice: experiences from the PRIME project." Australasian Psychiatry **23**(6_suppl): 35-37.

Shidhaye, R., S. Shrivastava, V. Murhar, S. Samudre, S. Ahuja, R. Ramaswamy and V. Patel (2016). "Development and piloting of a plan for integrating mental health in primary care in Sehore district, Madhya Pradesh, India." British Journal of Psychiatry **208 Suppl 56**: s13-20.

Shiell, A., P. Hawe and L. Gold (2008). "Complex interventions or complex systems? Implications for health economic evaluation." British Medical Journal **336**(7656): 1281-1283.

Siltanen, M., M. Aromaa, T. Hakulinen-Viitanen, R. Junnila, C. Laaksonen, H. Parisod and S. Salantera (2014). "A new participative, family-oriented health counseling approach for children and their families: a comparative qualitative analysis." Journal of Community Health Nursing **31**(2): 90-102.

Smith, N. and M. Barnes (2013). "New jobs old roles - working for prevention in a whole-system model of health and social care for older people." Health and Social Care in the Community **21**(1): 79-87.

Earl, S. and F. Carden (2002). "Learning from complexity: the International Development Research Centre's experience with outcome mapping." Development in Practice **12**(3-4): 518-524.

Statcorp (2013). STATA. College Station, Statcorp.

Stufflebeam, D. L. (2005). "CIPP model (context, input, process, product)." Encyclopedia of evaluation: 60-65.

Suarez-Balcazar, Y. (2005). "Empowerment and participatory evaluation of a community health intervention: Implications for occupational therapy." OTJR Occupation, Participation and Health **25**(4): 133-142.

Subba, P., N. P. Luitel, B. A. Kohrt and M. J. D. Jordans (2017). "Improving detection of mental health problems in community settings in Nepal: development and pilot testing of the community informant detection tool." Conflict and Health **11**: 28.

Sullivan, H., M. Barnes and E. Matka (2002). "Building Collaborative Capacity through `Theories of Change': Early Lessons from the Evaluation of Health Action Zones in England." Evaluation **8**(2): 205-226.

Sullivan, H., M. Barnes and E. Matka (2006). "Collaborative capacity and strategies in area-based initiatives." Public Administration **84**(2): 289-310.

Sullivan, H., K. Judge and K. Sewel (2004). "'In the eye of the beholder': perceptions of local impact in English Health Action Zones." Social Science and Medicine **59**(8): 1603-1612.

Sullivan, H. and M. Stewart (2006). "Who owns the theory of change?" Evaluation **12**(2): 179-199.

Summerfield, D. (2013). "“Global mental health” is an oxymoron and medical imperialism." British Medical Journal **346**: f3509.

Svoronos, T. and K. S. Mate (2011). "Evaluating large-scale health programmes at a district level in resource-limited countries." Bulletin of the World Health Organization **89**: 831-837.

Tait, L. and H. Lester (2005). "Encouraging user involvement in mental health services." Advances in Psychiatric Treatment **11**(3): 168-175.

Taplin, D., Clark H, E. Collins and C. DC. (2013). Theory of Change Technical Papers: A series of papers to support development of theories of change based on practice in the field. New York, ActKnowledge.

Taplin, D. H. and M. Rasic (2012). Facilitator's Source Book: Source Book for facilitators leading Theory of Change development sessions. New York, ActKnowledge.

Tanahashi, T. (1978). "Health service coverage and its evaluation." Bulletin of the World Health Organization **56**(2): 295.

Tansella, M. and G. Thornicroft (1998). "A conceptual framework for mental health services: the matrix model." Psychological Medicine **28**(3): 503-508.

Thara, R., S. John and S. Chatterjee (2014). "Community mental health teams in low- and middle-income countries." Epidemiology and Psychiatric Sciences **23**(2): 119-122.

The Indigo Network. (2018). "Indigo Primary." Retrieved 25th January 2018, from http://www.indigo-group.org/indigo-projects/project-3-improving-knowledge-attitudes-and-behaviour-of-primary-care-staff-towards-people-with-mental-illness-in-primary-care-settings-lead-dr-mirja-koschorke/.

Thornicroft, G., E. Brohan, D. Rose, N. Sartorius and M. Leese (2009). "Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey." The Lancet **373**(9661): 408-415.

Thornicroft, G. and M. Tansella (2013). "The balanced care model for global mental health." Psychological Medicine **43**(4): 849-863.

Thornicroft, G. and M. Tansella (2013). "The balanced care model: the case for both hospital- and community-based mental healthcare." British Journal of Psychiatry **202**(4): 246-248.

Tran, L. (2009) "A theory of change for mental health advocacy: a case study ". Retrieved 16th January 2014, from http://www.cesvol.org.uk/Resources/CharitiesEvaluationServices/Documents/kingsfundtoccasestudy-801-809.pdf.

Trani, J. F., E. Ballard, P. Bakhshi and P. Hovmand (2016). "Community based system dynamic as an approach for understanding and acting on messy problems: a case study for global mental health intervention in Afghanistan." Conflict and Health **10**(1): 1-11.

Tucker, P., Y. Liao, W. H. Giles and L. Liburd (2006). "The REACH 2010 logic model: an illustration of expected performance." Preventing Chronic Disease **3**(1): A21.

Ukoumunne, O. C., M. C. Gulliford, S. Chinn, J. A. C. Sterne and P. G. J. Burney (1999). "Evaluation of health interventions at area and organisation level." British Medical Journal **319**: 376-379.

Upadhaya, N., M. J. D. Jordans, R. Pokhrel, D. Gurung, R. P. Adhikari, I. Petersen and I. H. Komproe (2017). "Current situations and future directions for mental health system governance in Nepal: findings from a qualitative study." International Journal of Mental Health Systems **11**: 37.

US Department of Health and Human Services, Centres for Disease Conrol and Prevention, Office of the Director and Office of Strategy and Innovation (2011). Introduction to program evaluation for public health programs: a self study guide. Atlanta, GA, Centres for Disease Control and Prevention.

Valters, C. (2014). Theories of Change in International Development: Communication, Learning, or Accountability? Justice and Security Research Program Papers. London, The Asia Foundation.

Van Belle, S., R. van de Pas and B. Marchal (2017). "Towards an agenda for implementation science in global health: there is nothing more practical than good (social science) theories." BMJ global health 2(2): e000181.

Vandenbroucke, J. P., E. Von Elm, D. G. Altman, P. C. Gøtzsche, C. D. Mulrow, S. J. Pocock, C. Poole, J. J. Schlesselman and M. Egger (2007). "Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration." Annals of Internal Medicine **147**(8): 163-194.

Vander Stoep, A., M. Williams, R. Jones, L. Green and E. Trupin (1999). "Families as full research partners: what's in it for us?" Journal of Behavioral Health Services and Research **26**(3): 329-344.

Veerman, J. W., R. A. T. De Kemp, L. T. Ten Brink, N. W. Slot and E. M. Scholte (2003). "The implementation of families first in the Netherlands: A one year follow-up." Child Psychiatry and Human Development **33**(3): 227-244.

Vogel, I. (2012). Review of the use of 'Theory of Change' in international development. UK, Department for International Development (DFID).

von dem Knesebeck, O., L. Joksimovic, B. Badura and J. Siegrist (2002). "Evaluation of a community-level health policy intervention." Health Policy **61**(1): 111-122.

Walia, K., S. A. Belludi, P. Kulkarni, P. Darak and S. Swamy (2016). "A Comparative and a Qualitative Analysis of Patient's Motivations, Expectations and Satisfaction with Dental Implants." Journal of Clinical Diagnosis and Research **10**(4): ZC23-26.

Walker, J. S. and M. Matarese (2011). "Using a Theory of Change to Drive Human Resource Development for Wraparound." Journal of Child and Family Studies **20**(6): 791-803.

Walker, L. and L. Gilson (2004). "'We are bitter but we are satisfied': nurses as street-level bureaucrats in South Africa." Social Science and Medicine **59**(6): 1251-1261.

Walton, M. (2014). "Applying complexity theory: A review to inform evaluation design." Evaluation and Program Planning **45**(Supplement C): 119-126.

Warren, J., J. Wistow and C. Bambra (2014). "Applying qualitative comparative analysis (QCA) in public health: a case study of a health improvement service for long-term incapacity benefit recipients." Journal of Public Health **36**(1): 126-133.

Weiss, C. (1995). Nothing as Practical as Good Theory: Exploring Theory-based Evaluation for Comprehensive Community Initiatives for Children and Families. In New Approaches to Evaluating Community Initiatives: Concepts, Methods, and Contexts. J. Connell, P. Washington, DC, Aspen Institute. **:** 65-92.

Weitzman, B. C., T. Mijanovich, D. Silver and C. Brecher (2009). "Finding the Impact in a Messy Intervention: Using an Integrated Design to Evaluate a Comprehensive Citywide Health Initiative." American Journal of Evaluation **30**(4): 495-514.

Weitzman, B. C., D. Silver and K. N. Dillman (2002). "Integrating a comparison group design into a theory of change evaluation: The case of the urban health initiative." American Journal of Evaluation **23**(4): 371-385.

Wells, S., O. Tamir, J. Gray, D. Naidoo, M. Bekhit and D. Goldmann (2017). "Are quality improvement collaboratives effective? A systematic review." BMJ Quality and Safety: bmjqs-2017-006926.

Wenz-Gross, W. and T. DuBrino (2012). Central Massachusetts Communities of Care: Applying a Theory of Change Approach to Support Implementation, Evaluation, and Strategic Planning. Tools for Creating and Sustaining Human Services: Theory of Change Logic Models, University of South Florida

Whiteford, H. A., A. J. Ferrari, L. Degenhardt, V. Feigin and T. Vos (2015). "The Global Burden of Mental, Neurological and Substance Use Disorders: An Analysis from the Global Burden of Disease Study 2010." PLoS One **10**(2): e0116820.

WHO (2011). Mental Health Atlas 2011. Italy, World Health Organisation.

Wildschut, L. P. (2014). Theory-based evaluation, logic modelling and the experience of SA non-governmental organisations, Stellenbosch: Stellenbosch University.yamasaki

World Bank. (2012). "Countries and Economies " Retrieved 15th July, 2012, from http://data.worldbank.org/country/

World Health Organisation (2005). Mental health policy, plans and programmes. Mental health policy and service guidance package. Geneva, World Health Organization.

World Health Organization (2010). Mental Health Gap Action Programme Intervention Guide (mhGAP-IG) for mental, neurological and substance use disorders in non-specialized health settings. Geneva, World Health Organization.

World Health Organization (2011). Mental Health Atlas. Geneva, World Health Organization.

World Health Organization and World Organization of Family Doctors (2008). Integrating mental health into primary care: a global perspective. Geneva, World Health Organization.

Yamasaki, S. and B. Rihoux (2009). A Commented Review of Applications. Configurational comparative methods: Qualitative comparative analysis (QCA) and related techniques. B. Rihoux and C. Ragin. Thousand Oaks CA, Sage Publications.: 123-146.

Yin, R. K. (2009). Case Study Research: Design and methods, Thousand Oaks CA, Sage Publications.

Chapter 10. Appendices

1.1 Permission to include papers in PhD Thesis

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2.1 Systematic Review Protocol

3.1 Protocol for the ToC Workshops in PRIME countries

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4.4 PRIME Nepal ToC

4.5 PRIME South Africa ToC

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Appendix 1.1 Permission to include papers in PhD Thesis

From:	DOCTORAL DEGREES BOARD
To:	Erica Breuer; Erica Breuer
Cc:	Adri Winckler; Crick Lund
Subject:	Permission to Include Publications in PhD Thesis: Ms E Breuer JRSERI001
Date:	06 February 2018 11:10:08 AM
Attachments:	image001.png Declaration - Inclusion of publications.docx
Importance:	High

Dear Ms Breuer

I hereby confirm that the Chair of the Doctoral Degrees Board, Professor Phakeng, has **approved** your request to include the specified publications in your PhD thesis and noted the permission granted by the co-authors.

In your thesis (after your declaration that it is your own work) please include the following separate signed statement listing the publications that you were given permission to include: **"I confirm that I have been granted permission by the University of Cape Town's Doctoral Degrees Board to include the following publication(s) in my PhD thesis, and where co-authorships are involved, my co-authors have agreed that I may include the publication(s): "**

This declaration notifies examiners of the publications that you have been granted permission to include in your thesis.

Kind Regards

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Appendix 1.2 Ethics approval

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Human Research Ethics Committee
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Observatory 7925
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www.health.uct.ac.za/research/humanethics/forms

03 May 2013

HREC REF: 247/2013

Mrs E Breuer
c/o Prof C Lund
Department of Psychiatry & Mental Health
Room 46, Building B,
Child & Adolescent Psychiatry
46 Sawkins Road
Rondebosch, 7700

Dear Mrs E Breuer

PROJECT TITLE: USING THEORY OF CHANGE AS AN APPROACH TO DESIGNING, IMPLEMENTING AND EVALUATING COMPLEX MENTAL HEALTH INTERVENTIONS IN FIVE LOW AND MIDDLE INCOME COUNTRIES (link to 412/2011)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year till the 15 May 2014.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
sAriefdien

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

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Appendix 2.1 The use of Theory of Change to design, implement and evaluate Public Health Interventions: a systematic review protocol

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Erica Breuer, Lucy Lee, Mary De Silva, Crick Lund

1 Contents

v. Systematic Review Data Extraction Form

2 Aim and research questions

Aim

To explore and critically evaluate the literature on ToC and its use in the design, implementation and evaluation of PHIs

Research Questions

A systematic review will be used to identify, compare and evaluate studies which have used ToC for the design, implementation and/or evaluation of public health interventions (PHIs) to answer the following questions:

1) How do papers using ToC define ToC?
2) Do what extent do the papers who self-identify as using ToC report using the principles of Theory Driven Evaluation as identified by Coryn, Noakes et al. (2011) and the attributes of ToC identified by Vogel (2012).
3) How are programme theories for PHIs developed and refined in ToC approaches?
4) How does the ToC approach and the explicated programme theory influence the

a. Development of intervention;

b. Implementation of the intervention;

c. Development of indicators for measurement;

d. Evaluation of the intervention, including statistical approaches;

e. Conceptualisation/evaluation of influence of context; and

f. Causal attribution of the intervention?

3 Operational Definitions

Theory of Change (ToC): an outcomes-based approach which describes how an intervention brings about specific outcomes through a logical sequence of intermediate outcomes (Vogel 2012). ToC is distinct from sociological or psychological theories which describe why change occurs although these may be used to inform the ToC (De Silva, Breuer et al. (in preparation))

Interventions: *"a set of actions with a coherent objective to bring about change or produce identifiable outcomes. These actions may include policy, regulatory initiatives, single strategy projects or multi-component programmes."* (Rychetnik, Frommer et al. 2002)

Public Health Interventions (PHI): "*interventions [which] are intended to promote or protect health or prevent ill health in communities or populations. They are distinguished from clinical interventions, which are intended to prevent or treat illness in individuals."* (Rychetnik, Frommer et al. 2002)

The principles of Theory Driven Evaluation as identified by Coryn, Noakes et al. (2011) and the attributes of ToC identified by Vogel (2012) are outlined in Appendix iii and iv.

4 Data collection and tools

The systematic literature review will involve searching of the key databases of both peer-reviewed journal articles and other research outputs listed in Box 1, Figure 1.

Databases of Peer-Reviewed Journal Articles

- Scopus
- Pubmed
- PsychInfo
- Science Citation Index
- Social Science Citation Index
- Academic Search Premier
- Africa-Wide Information
- CINAHL
- BIOSIS

Databases of other research outputs (Grey Literature)

- The Directory of Published Proceedings
- Google (first 50 pages)
- OpenGrey
- PsycEXTRA
- Disability Archive UK
- Eldis
- Popline
- DFID Research for Development
- SciDevNet
- World Bank Documents and Reports

The websites of Comic Relief, DFID, Grand Challenges Canada, The Bill and Melinda Gates Foundation, HIVOS, World Vision, the Robert Wood Johnson foundation, Acktknowledge, and the Theory of Change Community will also be searched.

The search process will be recorded using a Database Search Log (Appendix i). As the purpose of the systematic review is to identify only those articles who report using ToC, I will search only for theory of change in all fields of the document. For databases which are not specific to healthcare I will also add the following search terms: health, health care, health services, and medicine.

To test the sensitivity of this search strategy, the search results will be checked for articles already identified from a previous systematic review of TDE by Coryn, Noakes et al. (2011). The review by Coryn et al. was much broader in scope than the proposed review and included any type of program evaluation in any discipline. It focused on whether studies using TDE adhered to the principles of TDE. Our study will investigate only ToC and how this has been used in the design, implementation and evaluation of public health interventions specifically. We will also investigate how the ToC approach was used in each stage of the programme development and evaluation.

In addition, reference sections of retrieved articles will be checked for further references and a citation analysis of key papers performed using the Scopus, Science Citation Index and

Social Science Citation Index. We will also include papers found through contacting experts in the field (Greenhalgh and Peacock, 2005).

Following the search, the titles and abstracts of the search results will exported into Endnote (Endnote 2011) where duplicates and irrelevant titles will be removed. Then the titles and abstracts will be screened by two reviewers, EB and LL using the Systematic Review Abstract and Full Text Screening Criteria (Appendix II).

Once the abstracts are screened for inclusion and exclusion criteria, the full papers will be obtained and assessed for eligibility by both reviewers. Papers that meet the inclusion and exclusion criteria will be included in the review and checked against the criteria proposed by Coryn, Noakes et al. (2011) for assessing papers reporting TDE and the components of ToC proposed by Vogel (2012) (Appendix iii). Studies will not be excluded on the basis of quality, but study quality will be used to assess possible heterogeneity in the results. Any differences between authors throughout the review process will be resolved via discussion.

The data from the content of the paper will be extracted by the first author (EB) using the attached form (Appendix v).

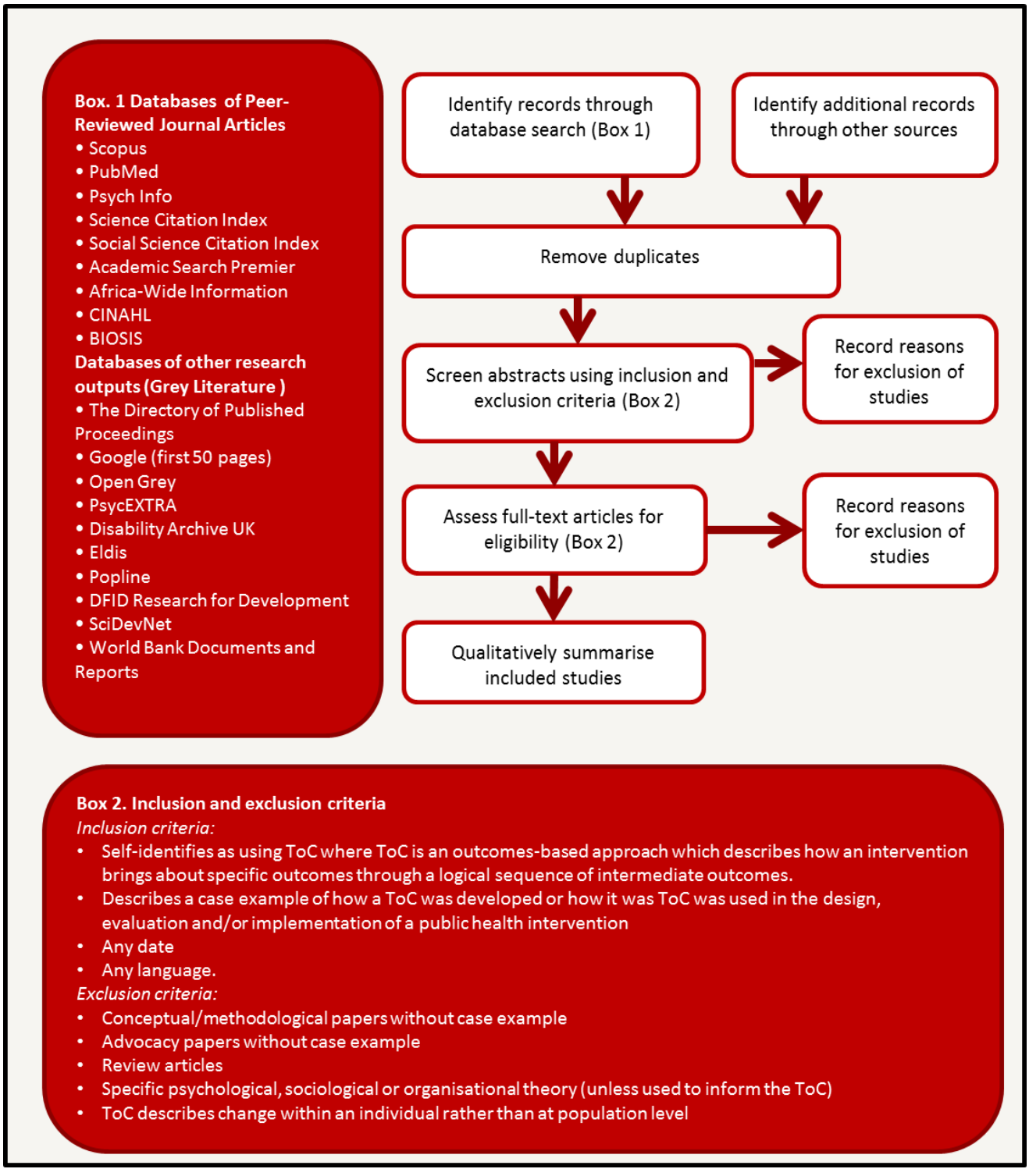


FIGURE 1 THE STAGES OF THE SYSTEMATIC LITERATURE REVIEW

5 Data analysis

Once the data is extracted, studies will be compared, evaluated and summarised qualitatively in relation to the research questions described above. Key lessons regarding the use of ToC for designing, implementing and evaluating PHIs will be synthesised.

6 Credibility and transferability

This review will employ various strategies to ensure that it is an unbiased representation of the literature. Firstly, a thorough *a priori* search strategy will be used to find relevant studies. We will include several databases specifically indexing grey literature in order to locate studies which are not reported in peer-reviewed journals. We will ensure our search strategy is adequate by checking the results against known articles which are relevant and by contacting experts in the field. Lastly, all potential abstracts and full text reports will be screened by two reviewers who will determine whether these studies should be included or excluded in the review.

Appendix: Data Collection Forms for the Systematic Review

i. Systematic Review Database Search Log

Database	Date	Search Strategy	No. of hits	Comments

ii. Systematic Review Abstract and Full Text Screening Criteria

Topic	Criteria	Yes	Unclear	No
Review article	Is this a review article?			
Public Health	Public Health intervention			
ToC	Self-identifies as using ToC where ToC is an outcomes-based approach which describes how an intervention brings about specific outcomes through a logical sequence of intermediate outcomes.			
	The ToC is not a specific organisational, sociological or psychological theory only (although the ToC may be based on one) but describes the public health intervention in question			
	The ToC explores changes within the population rather than within individuals			
	Uses ToC in the design, evaluation and/or implementation of an intervention			
Advocacy/methodological paper only	Does it include a case example?			

Instructions

Abstract screening

- Find Full Text if Review (No/Unclear) AND TOC (Yes/Unclear to all) AND Public Health (Yes/Unclear)
- Exclude if Review (Yes) OR TOC (No to any) OR Public Health (No)
- Exclude if advocacy/methodological paper with no case example

Full text screening

- Include full text in review if review (No) AND TOC (Yes to all) AND Public Health (Yes)
- Exclude if Review (Yes) OR TOC (No to any) OR Public Health (No)
- Exclude if advocacy/methodological paper with no case example

For full text screening the order of the inclusion and exclusion criteria will be changed to increase efficiency. The criteria remained the same.

iii. Systematic Review Quality Assessment form for Theory-Driven Evaluation Papers

Criteria (Adapted from Coryn, Noakes et al. (2011))		Yes	Page #	No	Not enough detail provided	Comments
A	**Theory formulation**					
	Programme theory is formulated					
A1	from existing theory and research					
A2	from implicit theory					
A3	from observation of the program in operation/exploratory research					
B	**Theory-guided question formulation and prioritisation**					
B1	Evaluation questions were formulated around program theory					
B2	Evaluation questions were prioritised	Yes		No		
B3	Evaluation questions are prioritised according to:	Funding priorities		Logistical constraints	Programme theory	
		Other		Describe:		
C	**Theory-guided planning, design, and execution**					
C1	A programme theory is used to design, plan and conduct evaluation					
C2	Programme theory is used to determine whether the evaluation was designed considering relevant contingencies					
C3	Programme theory was used to determine whether the evaluation should be tailored or comprehensive					
D	**Theory-guided construct measurement**					
D1	Process constructs postulated in programme theory are measured					

D2	Outcome constructs postulated in programme theory are measured					
D3	Contextual constructs postulated in programme theory are measured					
E	**Identification of breakdowns and side effects, effectiveness or efficacy, and causal explanation**					
E1	Breakdowns of programme theory are identified					
E2	Outcomes were identified which were NOT postulated by program theory					
E3	Cause-and-effect associations between theoretical constructs are described					
E4	Cause-and-effect associations between theoretical constructs are explained					
E5	Differences in direction and/or strength of relationship between program and outcomes are explained					
E6	The extent to which one construct accounts for/mediates the relationship between other constructs is explained					

iv. Systematic Review Quality Assessment form for core elements of ToC

Core elements of a ToC (Adapted from Vogel (2012))		**Yes/No**	**Page No**
Context	for the initiative, including social, political and environmental conditions and other actors able to		

	influence change
Long-term change	that the initiative seeks to support and for whose ultimate benefit
Process/sequence of change	that is anticipated in order to create the conditions for the desired long-term outcome
Assumptions	about how these changes might happen, as a check on whether the activities and outputs are appropriate for influencing change in the desired direction in this context.
Diagram and narrative summary	that captures the outcomes of the discussion.
Additional Components	
Beneficiaries	Focus on who is intended to benefit from the changes in the context that the programme or intervention aims to support, and how they will benefit.
Actors in the context	Analysis of the actors, organisations and networks that influence change in the setting, power relationships and institutional configurations
Sphere of influence	Analysis of the programme's, ability to reach and influence change, directly through its interventions or indirectly through collaboration and interaction
Strategic choices and intervention options	Activities needed to influence the changes sought
Timeline	A realistic timeframe for changes to unfold, expected trajectory of changes following interventions
Indicators	Areas to investigate and track with evaluation and impact assessment.

v. Systematic Review Data Extraction Form

Variable	Response
Reference	[text]
Year	[number]
Language	[text]
Location(s)	[text]
Type of publication	[Grey (1) /Postgrad Dissertation (2)/Published- peer reviewed (3)]
Journal	[text]
Journal Field	[text]
Brief description of programme	[text]
Integrated into routine health services	[yes/no]
Mental Neurological and Substance Use intervention	[yes/no]
Set in low and middle income country	[yes/no]
Type of health intervention	[text]
Health outcome	[text]
Other outcomes	[text]
Describes development of TOC	[yes/no]
How was the TOC developed?	[text]
Retrospective or prospective theory development	[retrospective/prospective/neither]
How are TOC for PHIs refined?	[text]
Describes Role of ToC in development of intervention	[yes/no]

Role of TOC in: The development of the intervention	[text]
Describes role of ToC in the implementation of the intervention	[yes/no]
Role of TOC in: Implementation of the intervention	[text]
Describes the Role of ToC in the evaluation of the intervention	[yes/no]
Role of TOC in: Development of indicators for measurement	[text]
Role of TOC in: Evaluation of the intervention, including statistical approaches	[text]
More detail on statistical analysis	[text]
Role of TOC in:Influence of context	[text]
Role of TOC in: Causal attribution of the intervention	[text]
Role of TOC in generalising the results to other programmes	[text]
Potential Biases or concerns	[text]
Other points or key lessons for reflection from the authors	[text]
Notes	[text]

References

Coryn, C. L. S., L. a. Noakes, C. D. Westine and D. C. Schroter (2011). "A Systematic Review of Theory-Driven Evaluation Practice From 1990 to 2009." American Journal of Evaluation **32**: 199-226.

De Silva, M., E. Breuer, L. Lee, C. Lund and V. Patel ((in preparation)). "Theory of change: a theory-driven approach to the MRC framework for complex interventions ".

Endnote (2011). San Fransisco, Thomson Reuters.

Rychetnik, L., M. Frommer, P. Hawe and A. Shiell (2002). "Criteria for evaluating evidence on public health interventions." Journal Of Epidemiology And Community Health **56**: 119-127.

Vogel, I. (2012). Review of the use of 'Theory of Change' in international development. UK, Department for International Development (DFID).

Appendix 3.1 Protocol for the ToC Workshops in PRIME countries

1.1.1 Introduction

Theory of Change (ToC) is "a theory of how and why an initiative works" (Weiss, 1995). It can also be thought of as your theory, or 'story' of how the intervention will make change in the world.

ToC was developed in the 1990s as a means to develop and evaluate comprehensive community initiatives within the US based Aspen Institute Roundtable on Community Change (Aspen Institute, 1997).

Although ToC has not yet been widely used in the evaluation of complex interventions to improve health, it holds much promise for this. Using ToC in tandem with the MRC framework for the evaluation of complex interventions (Craig 2008) will ensure a theory-driven approach to the development, evaluation and implementation of complex interventions.

1.1.2 Aim

To use the ToC approach to elicit stakeholder opinion and buy-in on the development of a feasible mental health care plan.

1.1.3 Objectives

1. To map out a realistic ToC with stakeholders that will improve health, social and economic outcomes in people living with priority disorders in the selected administrative health units (AHUs).
2. To clarify the assumptions of this plan with stakeholders.
3. To generate research questions to answer the assumptions in (2).
4. To elicit stakeholder buy-in and consensus on the ToC map.
5. To record the process of the development of the ToC and to compare this across countries.

1.2 Methods

ToC workshops will be held in each PRIME country. There will be at least two ToC Workshops: a preliminary Theory of Change Workshop (PToC) and a final Theory of Change Workshop (FToC).

1.2.1 Sample

In all countries, the ToC workshop(s) will include diverse stakeholders and will consist of representatives of at least:

1) District managers
2) Primary health care service providers, including physicians, clinical officers, nurses and community health workers (exact health worker types to depend on country contexts)
3) Mental health coordinator (or equivalent) for the district eg mental health nurse/clinical officer

4) A member of the community advisory board
5) Disorder specific stakeholders for the disorder specific workshop(s) if relevant to the country, e.g. district psychosocial rehabilitation providers. If it is feasible within the country context, additional stakeholders such as community or national level stakeholders or advisors should be included.

Due to power differentials across levels of the health systems, countries may choose to hold more than one workshop with the above participants. In addition countries may choose to hold a workshop at the community and national level. However if multiple ToC workshops are conducted at different "levels" there should be communication between these levels so that what finally emerges is endorsed by all participants, and is a product of all of their contributions. In this way the input of multiple stakeholders can be consolidated.

Purposive sampling will be used to identify participants for the theory of change workshops. 8-10 participants will be included in each Theory of Change Workshop. We will ask potential participants at least one week prior to the focus groups if they would like to participate. At this time we will give them a brief information sheet (ToC Protocol Annex 1) to explain the purpose of the project, the potential risks and benefits and will clearly state that the person has no obligation to participate and can withdraw at any time. We will ask them to read and think about the consent and then inform us if they are happy to attend. If they choose to attend, they should bring the signed consent form (ToC Protocol Annex 2) with them or be prepared to sign prior to joining the Theory of Change workshop.

1.2.1.1 Preliminary Theory of Change Workshop (PToC)

The PToC are designed to meet all of the above objectives, particularly 1, 2 and 3.

These workshop(s) will be based on a simplified outcome map derived from the generic ToC template generated by the PRIME group.

The workshop(s) will begin by introducing the concepts and preconditions of scaling up for mental health care that we have developed in PRIME. These include the use and adaptation of mhGAP, priority disorders and integrated mental health care in a pyramidal model of community/facility/health care organization, as laid out in the proposal), an introduction to the ToC principles and the framework of the ToC template (Figure 1).

Prior to discussion of the disorder specific ToC there will be discussion of the disorder, contextualised for the setting, for example, burden of disease, impact, pathways to care, explanatory models, current care and treatment gaps.

	Political buy in	Budget	Availability of medications	HIS available	Human resources	Capacity building	MH awareness and stigma	Identification	Service delivery	Long term outcome	Impact
Healthcare organisation											
Healthcare facility											
Community											

FIGURE 1 FRAMEWORK OF THE TOC TEMPLATE

The workshops will begin by discussing the meaning of the impact and agreeing whether this is achievable and realistic. Thereafter, the group will work forwards from beginning through each step of the outcome map, looking specifically at:

a) Outcomes: defining these clearly and considering the extent to which they are achievable and realistic.

b) Rationale: does each outcome lead logically to the next outcome in the ToC map? If not, are additional intermediary outcomes needed, or a different kind of intervention to move from one outcomes to the next? Is more formative research needed before we can be confident that one outcome logically leads to the next in this setting?

c) Assumptions: what needs to be in place for the outcomes to occur?

d) Interventions: at which point are interventions necessary to lead from one outcome to the next. It should be clear during the workshop that the interventions will have their basis in the mhGAP recommendations plus additional interventions where required.

e) Establishing vertical and horizontal lines of accountability of the Theory of Change

To ensure all aspects are covered, it is recommended that the facilitator highlights the following topics as key areas for consideration in the ToC where relevant to the stakeholder group: buy in, budget, availability of medications, health information systems human resources, capacity building, mental health awareness and stigma, identification of mental illness and service delivery.

The discussion should include both the overarching map for pathways to care as well as disorder specific pathways to care. The order in which these are discussed can be determined by the facilitator. For example, it is possible to discuss the disorder specific ToCs first then generate an overall ToC for all disorders, or agree on a generic ToC based on the PRIME template, and then modify accordingly for each disorder, with iterations back to the generic template to make modification as the need arises.

The anticipated time to complete the workshop is two days.

The outputs from the PToC workshop(s) will be:

1. A preliminary disorder specific Theory of Change map for:
    a) Depression
    b) Psychosis
    c) Alcohol use
    d) Epilepsy, where applicable
    e) Maternal depression, where not included in Primary Health Care setting
2. A preliminary overarching Theory of Change map.
3. A list of additional country research questions generated by the Theory of Change workshop(s)

1.2.1.2 Final Theory of Change Workshop (FToC)

The objective of the final ToC workshop is to elicit stakeholder buy in and consensus on the ToC map. It will include the same stakeholders who were involved in the preliminary Theory of Change Workshop, plus other important stakeholders who may have been identified subsequently.

The workshop will include a short summary of the preliminary ToC maps, both the disorder specific and overarching ToC, and a reminder of the principles of the ToC. The assumptions and rationale will be reviewed with the group with the results from the formative research and the interventions will be added where applicable. Consensus will be sought from the participants on whether the ToC maps are achievable and realistic in their setting and modifications will be made where necessary.

The outputs from the FToC workshop(s) will be:

1. A final disorder specific Theory of Change map for:
    a) Depression
    b) Psychosis
    c) Alcohol use
    d) Epilepsy, where applicable
    e) Maternal depression
2. A final overarching Theory of Change map.

1.3 Documentation

The ToC workshops will be documented using:

a) Participant questionnaires (Appendix 3) which will be administered prior to the commencement of the workshop, following the distribution of patient information sheets (Appendix 1) and informed consent (ToC Protocol Annex 2).
b) Detailed note taking, see note-taking guideline (ToC Protocol Annex 3)
c) Analysis of the types of changes and comments to the ToC map.
d) Structured interviews with facilitators following the workshop

e) Where feasibility and consent allow, the workshops will be recorded using audio or audiovisual equipment.

1.5 ToC Protocol Annex 1: Participant information sheet

Theory of Change Workshop

Programme for Improving Mental Health Care (PRIME)

This may need to be modified, depending on the stakeholder group and country context and used with local consent form.

You are being invited to take part in a Theory of Change Workshop as part of a research programme called the Programme of Improving Mental Health Care. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

The Programme for Improving Mental Health CarE (PRIME) is a six year research programme funded by the Department for International Development (DFID) which aims to generate world-class research evidence on integrating treatment programmes for depression, alcohol use disorders, psychosis [AND EPILEPSY] into primary and maternal health care contexts. We are working in Ethiopia, India, South Africa, Uganda and Nepal. In [INSERT COUNTRY HERE] we are working in the [INSERT DISTRICT HERE].

To achieve this aim, we will be developing an integrated mental health care plan for delivery in primary health care and maternal health care. This plan will be put into effect and evaluated in one district in [INSERT DISTRICT HERE]. We will then adapt the plan as necessary and test the plan in at least two additional districts by the end of the six year period.

The PRIME Theory of Change workshops are designed to include people who have experience in various aspects of the primary health care system and/or the [xxxxxxxx] district to contribute their experience to our mental health care plan.

Why have I been invited to participate?

You have been invited to participate because of your experience in the health care system or related areas. We value your opinion about what is possible in [INSERT DISTRICT NAME HERE] and would greatly appreciate your help in planning how we should implement this project.

We are inviting 8-10 people to attend this workshop.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason and your decision will be kept confidential and will not disadvantage you in any way.

What will happen to me if I take part?

You will be asked to attend a two day workshop on _____ and a half day follow up workshop in _____.

The workshop will begin by introducing some background on mental health care and how it can be integrated into primary and maternal health care. Thereafter we will ask you to look at a diagram of how we think we can improve mental healthcare at a healthcare organisation, health facility and community level and the steps needed to do this. We will ask you to give your opinion about this

and whether it would work in [xxxxxxx] district and what might be done to increase the chance of success.

Once we have looked at the overall plan, we will also look at each disorder, namely depression, alcohol use, psychosis [AND EPILEPSY], and see whether the plan needs adaptation for these specific disorders.

What are the possible disadvantages and risks of taking part? (where appropriate)

As a result of taking part in this study, you will need to be available for the 2 day Theory of Change Workshop. We will also invite you to a follow up theory of change workshop as well as the half day follow up workshop in a few months time. At this workshop you will be asked to express your opinion about the Theory of Change diagram in a group setting. Although we will ask participants to keep what is said in the room confidential, we cannot guarantee that they will do this.

We do not anticipate any physical or emotional risks as part of this study.

What are the possible benefits of taking part?

Having a well thought out mental health care plan for [xxxxxx] district will benefit the clinics in the district by improving mental health care provision. We do not anticipate any direct benefits to you, although you may find the process interesting and informative.

Will what I say in this study be kept confidential?

All information collected about you will be kept strictly confidential (subject to legal limitations). Your identity will be anonymous and following analysis of the data, the tapes

and transcripts will be destroyed. The data will only be seen by the researchers and investigators. The study documentation will be kept on password protected computers and locked filing cabinets for 7 years. Your name will not appear on any publication arising from this research.

What should I do if I want to take part?

If you would like to participate, please let [PROJECT CO-ORDINATOR] know via [MODE OF COMMUNICATION] before the [DATE]. [PROJECT CO-ORDINATOR] will confirm the time and place of the Theory of Change Workshops. Please bring a copy of your signed consent form to the Theory of Change Workshop.

What will happen to the results of the research study?

The results of the study will be published in the scientific literature and used to inform the mental health care plan. We will also share this information with policy makers via policy briefs. For a copy of published research, please contact [PROJECT CO-ORDINATOR] via [MODE OF COMMUNICATION]

Who is organising and funding the research?

The research in [COUNTRY] is being organised by [COUNTRY PARTNER, COUNTRY PARTNER CONTACT DETAILS]. The research is being funded by the Department of International Development in the United Kingdom.

Who has reviewed the study?

The study has been approved by [name of ethics committee]

Contact for Further Information

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

[CONTACT]

If they have any concerns about the way in which the study has been conducted, they should contact the [CHAIR OF ETHICS COMMITTEE] via [MODE OF COMMUNICATION]

Thank you for taking the time to read this information sheet.

9th January, 2012

1.6 ToC Protocol Annex 2: Example of a Consent Form

Country specific consent forms will be used here. This example is the consent form used at the South African site.

Consent to Enroll

I, _____ agree to participate in the research study on understanding mental disorders in the Dr Kenneth Kuanda district to understand culturally and contextually appropriate ways for treating these disorders. I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the workshops as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred fpr psychological help if need be.

Signature: _____

Name: _____

Date: _____

Witness 1

Signature: _____

Name: _____

Date: _____

Witness 2

Signature: _____

Name: _____

Date: _____

You may keep the information sheet. The signed consent form will remain in our study files.

1.7 ToC Protocol Annex 3: Participant Questionnaire

Theory of Change Workshop Participant Questionnaire

Programme for Improving Mental Health Care (PRIME)

Participant No: _____

1. Gender Male / Female

2. Current Position / Post _____

3. Time in current post: ___ ___ years

4. Mental health training: Yes / No

    a. If yes, how long did the training last? ___ ___ weeks

b. How long ago did you have the training? ___ ___ years

5. Experience in planning or delivering primary health care (describe):

6. Experience in planning or delivering maternal health care (describe):

7. Experience in planning or delivering mental health care (describe):

8. Other relevant experience

1.8 TOC Protocol Annex 4: Note taking guidelines

We would recommend that the research team have a dedicated note taker, who is not involved in facilitation or participation in the meeting. The note taker should:

1) Record an outline of the process
2) Record the opinion of stakeholders around the different elements of the ToC, i.e.
    a. Impact
    b. Outcomes
    c. Rationale
    d. Assumptions
    e. Interventions

    This is particularly important when members of the group do not agree.

3) Record the amount of participation of each participant in the ToC Process.

Appendix 3.2 Questionnaires for interviews with facilitators/principal investigators

a. Semi-structured interview guide: Feedback from preliminary PRIME Theory of Change Workshop

a) Participants

i. Who did you ask to participate in the workshop?

i. What are your reasons for choosing this group of people?

ii. Are there people you would have liked to include but weren't able to due to logistical constraints?

b) Workshop structure

i. How was the ToC workshop structured, i.e. how was the workshop introduced? Did you start with the generic or disorder specific Theory of Change?

ii. Were all the elements, i.e. outcomes, assumptions, rationales and interventions, considered for each step of the outcome map. Were there any unexpected comments? Did this lead to a significant shift in the ToC map?

c) Group dynamics

i. What the dynamic of the group was like?

i. Did only 2 or 3 members of the group participate or did all of the group participate equally?

ii. What were the power dynamics between different groups of stakeholders?

ii. Was consensus reached in all situations?

i. How was it reached?

ii. What happened when consensus was not reached?

d) Usefulness of the process

i. How do you think the participants view the workshop?

i. Did they find it useful?

ii. Was it an effective way of getting stakeholder buy-in for the project?

ii. Did the group find working on the disorder specific ToCs or the generic ToC more useful?

iii. Were research questions generated as part of this process?

i. If so, what topics were they centred around?

iv. Was consensus reached on the disorder specific ToC maps and the overarching ToC map?

v. Did the workshops help you to clarify your thinking around the draft MH plan? How?

vi. How did you see your role as a facilitator? What worked well? What would you do differently next time?

e) Documentation

i. Did you manage to have all participants fill out an questionnaires about themselves and a consent form?

ii. Did you manage to record the workshop using audio or video tape?

iii. Did you have someone involved in taking notes?

f) Moving forward

i. Do you think that this workshop was adequate to generate a comprehensive ToC map?

ii. Are you still planning additional ToCs at this preliminary stage?

i. If so, what is your plan in terms of sampling?

iii. Are you planning on having a final ToC workshop after the formative research is finished?

i. Will you include the same people as participants?

b. Semi-structured interview guide: Feedback from final Theory of Change Workshop

a) Participants

i. Who did you ask to participate in the workshop?

i. What are your reasons for choosing this group of people?

ii. Are there people you would have liked to include but weren't able to due to logistical constraints?

iii. Were they the same group as your preliminary ToC workshop?

b) Workshop structure

i. How was the ToC workshop structured, i.e. how was the workshop introduced?

ii. Were all the elements, i.e. outcomes, assumptions, rationales and interventions, considered for each step of the outcome map. Were there any unexpected comments? Did this lead to a significant shift in the ToC map?

iii. Did you determine the indicators for the ToC?

c) Group dynamics

iii. What the dynamic of the group was like?

i. Did only 2 or 3 members of the group participate or did all of the group participate equally?

ii. What were the power dynamics between different groups of stakeholders?

iv. Was consensus reached in all situations?

i. How was it reached?

ii. What happened when consensus was not reached?

d) Usefulness of the process

i. How do you think the participants view the workshop?

i. Did they find it useful?

ii. Was it an effective way of getting stakeholder buy-in for the project?

ii. Were research questions generated as part of this process?

    i. If so, what topics were they centred around?

iii. Was consensus reached on the disorder specific ToC maps and the overarching ToC map?

iv. Did the workshops help you to clarify your thinking around the draft MH plan? How?

v. What did you like about the process of developing the TOC?

vi. What did you find difficult or challenging?

vii. How did you see your role as a facilitator? What worked well? What would you do differently next time?

e) Documentation

i. Did you manage to have all participants fill out an questionnaires about themselves and a consent form?

ii. Did you manage to record the workshop using audio or video tape?

iii. Did you have someone involved in taking notes?

f) Moving forward

i. Do you think that this workshop was adequate to generate a comprehensive ToC map?

ii. Are you still planning additional ToCs at this stage?

    i. If so, what is your plan in terms of sampling?

iii. Are you planning on having a final ToC workshop after the formative research is finished?

    i. Will you include the same people as participants?

iv. How do you see yourselves using the TOC in the implementation phase?

v. Would you use the TOC again?

c. Semi-structured interview guide: Feedback from the principal investigators and project co-ordinators following the finalisation of the Mental Health Care Plans

Now that your Mental Health Care Plans have been finalised, I thought it would be valuable to reflect on the development of the plan and the different components which assisted this process and then move on to talk specifically about the Theory of Change process in your country.

Mental Health Care Plans

1) Could you briefly describe the how your mental health care plan is structured?

2) How have the following methods contributed to the development of the MHCP? What were the advantages and disadvantages of these methods and what sort of information could you gain from them.

   Probe for various aspects of the plan, i.e. the overall goals and objectives of the plan, the content of the plan, tasks, human resources, budgets/financing, Indicators and evaluation design, standard operating procedures

   a. Situational analysis
   b. Formative work (policy makers, service providers and community members)
      i. Semi structured interviews
      ii. Focus Group Discussions
   c. The costing tool
   d. Piloting (if applicable)
   e. ToC workshops and development of the ToC

   Probe for any other methods which you used in the planning:

   If yes,

f. What were the advantages and disadvantages of these methods and what sort of information could you gain from them.

3) Did the different approaches play different roles and if so, how did they work

   Probe for situational analysis and formative work providing data on substance, costing tool providing data on resources, and ToC providing an organising framework for understanding how the different components of the plan are intended to lead to the desired outcome etc.

4) How do all of these approaches work together to inform your plan? Were any approaches superfluous or did they all yield new information?
5) What do you think the specific role of ToC was? Did it provide a helpful organising framework for thinking about your mental health care plans? What makes it different to the other approaches?
6) How did you ensure that the plan was contextually relevant?
7) Do you think the district and facility stakeholders feel ownership of your plan? How did you achieve this?

Theory of Change

Thinking specifically about the ToC process (this includes the workshops as well as the development and refining of the maps), could you give me some more detail:

1) Could you describe the elements of the overall ToC process in your country? How you planned and developed the ToC – this could be through stakeholders workshops or otherwise? How did you go on to refine it? Where do you see the ToC going from here?
2) What do you feel is the value of using the ToC process to assist with the development of the MHCP? What aspects of the plan did it assist with which were not covered by other approaches?
3) In what way did the ToC hinder the process of developing the MHCP? (e.g. was it an added/unnecessary burden on the team/investigators?)

4) Were there any barriers which stopped you from using ToC effectively? Was there anything which helped you to use ToC effective or more effectively?
5) What do you feel is the value of using the ToC process to assist with the evaluation of the MHCP (including the design of the evaluation)?
6) Did you use the ToC to develop the set of indicators you wanted measure? How did this compare to the using the MHCP functions as an outline for the development of the indicators?
7) In what way did the ToC hinder the evaluation design?
8) Was there anything which hindered you from using ToC effectively? Was there anything which helped you to use ToC more effectively?
9) What do you think are the gaps in the ToC approach? What could it include or focus more on? How would you use it if you used it again?
10) How much time and resources did you invest in using this approach? How much time did you spend on the workshops (pre-workshop, preparation, follow on work)? How much of this time was spent drawing and refining the ToC map itself? Do you feel that this was worth the investment in time and resources? Why; or why not?
11) How do you see the relationship between your country ToC and your MHCP? Do you think the ToC reflects your MHCP? How? Or why not?
12) How do you see the relationship between your country ToC and the PRIME generic ToC? Do you think the cross country ToC reflects your own ToC? How? Or why not?
13) Do you think the PRIME generic ToC adds value over and above the country ToC? What specifically does it provide? Or why not?
14) What are your further plans for the use of Theory of Change? For example, are you planning to refine your ToC after the evaluation phase (i.e. when ToC has been comprehensively evaluated)? How do you think this will inform your scaling up phase?

15) Would you use the ToC approach again if you were planning a similar intervention. Would you use it in the same way? What would you change? Would you also use all the additional methods used in PRIME – why/why not?

d. Participant Information Sheet for PIs and facilitators

Participant information sheet

Programme for Improving Mental Health Care (PRIME)

The Programme for Improving Mental Health CarE (PRIME) is a six year research programme funded by the Department for International Development (DFID) which aims to generate world-class research evidence on integrating treatment programmes for depression, alcohol use disorders, psychosis into primary and maternal health care contexts. We are working in Ethiopia, India, South Africa, Uganda and Nepal.

To achieve this aim, we are using a Theory of Change (ToC) approach to assist with the design, implementation and evaluation of the mental health care plans.

In order to understand the process of the workshops in each country and as part of ongoing feedback to the consortium, we invited you to participate in interviews following each workshop (or set of workshops) at the preliminary, final and follow up ToC workshops. We would like to use a framework analysis to analyse these interviews and to determine the differences and similarities between the workshops and across countries and generate a set of key lessons from the facilitation of the workshop.

a. Do I have to take part?

It is up to you to decide whether or not your interviews are used as part of study. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason and your decision will be kept confidential and will not disadvantage you in any way.

b. What will happen to me if I take part?

The interviews will continue as part of the feedback mechanism of PRIME. You will be contacted by Erica Breuer to arrange a telephonic interview following the preliminary, final and follow up workshop (or set of workshops) and after the finalising the Mental Health Care Plan. These will be recorded, transcribed, analysed and written up for publication.

c. What are the possible disadvantages and risks of taking part? (where appropriate)

We do not anticipate any physical or emotional risks as part of this study.

d. What are the possible benefits of taking part?

Your country's ToC process will be included in the cross country analysis and one person, usually the primary facilitator of the workshops will be nominated by the principal investigator of each country to be included as an author on the paper. We do not anticipate any direct benefits to you, although you may find the process interesting and informative.

e. Will what I say in this study be kept confidential?

All information collected about you will be kept strictly confidential (subject to legal limitations). Following analysis of the data, the tapes and transcripts will be destroyed. The data will only be seen by the researchers and investigators. The study documentation will be kept on password protected computers and locked filing cabinets for 7 years.

f. What should I do if I want to take part?

If you would like your interviews to be used as part of this research, please fill in and sign the consent form attached and send to Erica Breuer via email at (erica.breuer@uct.ac.za).

g. What will happen to the results of the research study?

The results of the study will be published in the scientific literature and used to inform future planning workshops. We will also share this information with policy makers via policy briefs. We will

keep you informed of any papers published from this research. For a copy of published research, please contact Erica Breuer (erica.breuer@uct.ac.za or 021 658 1223)

h. Who is organising and funding the research?

This research is being organised by A/Prof Crick Lund and Ms Erica Breuer from the University of Cape Town as part of PRIME funded by the Department of International Development in the United Kingdom.

i. Who has reviewed the study?

The study has been approved by the Faculty of Health Sciences Human Research Ethics Committee at the University of Cape Town.

j. Contact for Further Information

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

Erica Breuer

Alan J. Flisher Centre for Public Mental Health

University of Cape Town

46 Sawkins Road

Rondebosch, 7700

South Africa

Phone: +27 21 685 1223

Email: erica.breuer@uct.ac.za

If you have any concerns about the way in which the study has been conducted, you should contact the A/Prof Marc Blockman, chair of the Faculty of Health Sciences Human Research Ethics Committee at the University of Cape Town:

A/Prof Mark Blockman

Chair

Faculty of Health Sciences Human Research Ethics Committee

Old Main Building

Groot Schuur Hospital

University of Cape Town.

Observatory

Tel: 021 406 6333

Marc.Blockman@uct.ac.za

Thank you for taking the time to read this information sheet.

Consent to Enroll

I, _____ agree that my feedback interviews from the ToC workshops can be transcribed and analysed as part of the research described in the information sheet above. I have received and understood the participant information sheet. I have discussed the advantages and disadvantages of participating in the study.

I know I can leave the research study at any time without prejudice.

Signature: _____

Name: _____

Date: _____

Witness

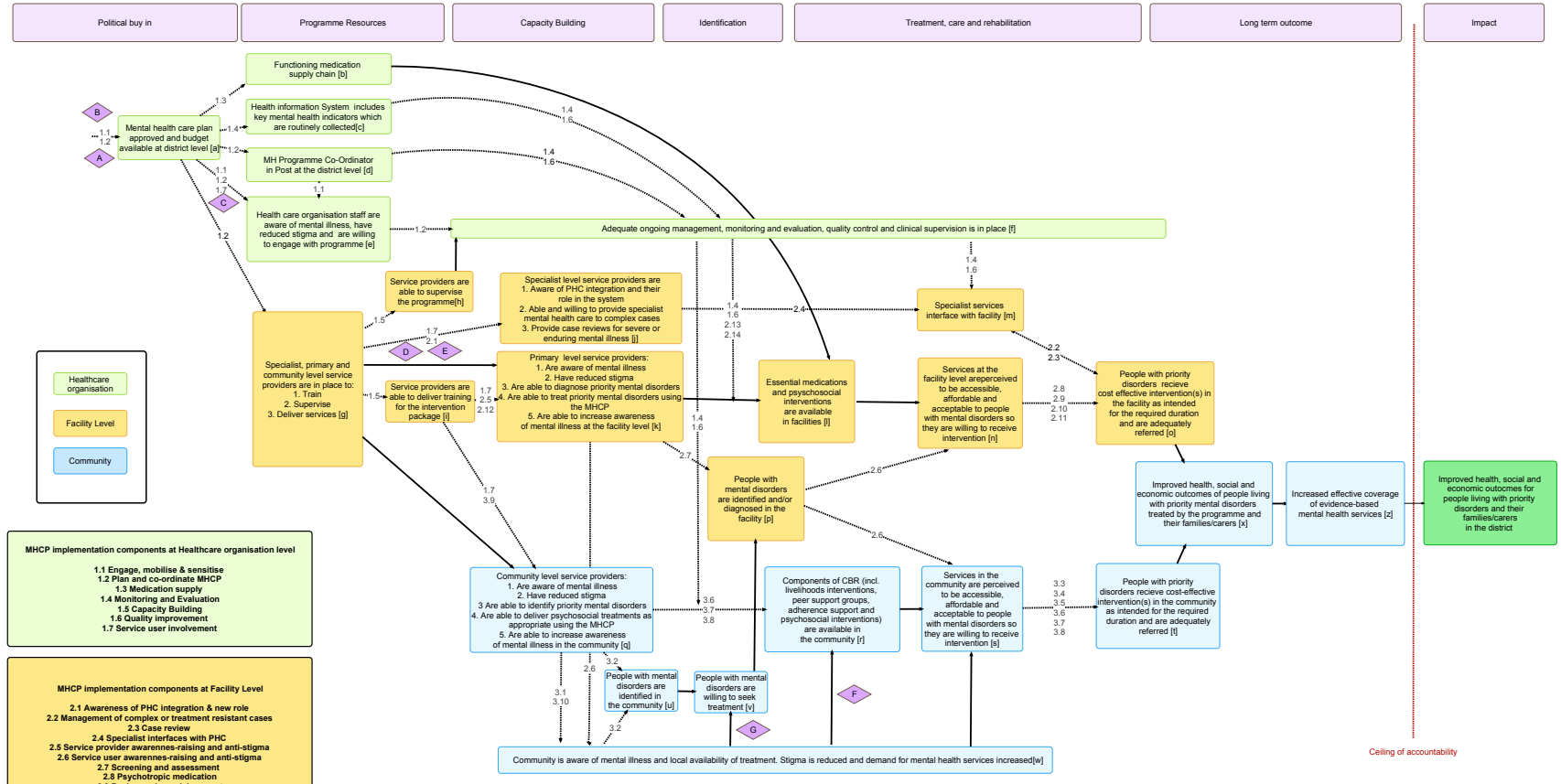
Signature: _____

Name: _____

Date: _____

You may keep the information sheet. The signed consent form will remain in our study files.

Appendix 4.1 PRIME Cross Country ToC and Indicators



MHCP implementation components at Healthcare organisation level

1.1 Engage, mobilise & sensitise
1.2 Plan and co-ordinate MHCP
1.3 Medication supply
1.4 Monitoring and Evaluation
1.5 Capacity Building
1.6 Quality improvement
1.7 Service user involvement

MHCP implementation components at Facility Level

2.1 Awareness of PHC integration & new role
2.2 Management of complex or treatment resistant cases
2.3 Case review
2.4 Specialist interfaces with PHC
2.5 Service provider awarennes-raising and anti-stigma
2.6 Service user awarennes-raising and anti-stigma
2.7 Screening and assessment
2.8 Psychotropic medication
2.9 Basic psychosocial support
2.10 Advanced psychosocial support
2.11 Continuing care
2.12 Health facility staff capacity building
2.13 Emotional support for PHC workers
2.14 Supervision for PHC workers

MHCP implementation components at Community Level

3.1 Community awarenness raising
3.2 Community detection
3.3 Basic psychosocial support
3.4 Advanced psychosocial support
3.5 Peer support groups
3.6 Outreach and adherence support
3.7 Rehabilitation and reintegration
3.8 User group mobilisation
3.9 Community capacity building
3.10 Inter-sectoral linkages

Assumptions

A. The district is adequately funded
B. Committed leadership at national, state and/or district level.
C. HCO staff are willing to participate in awareness and sensitization
D. Specialist, primary and community level providers are engaged with the programme and willing to participate in providing and/or receiving training and supervision without monetary incentives
E. Trained staff remain in post and new staff are trained
F. Community Based Organizations willing to collaborate in CBR
G. Opposition from complimentary healers does not cause undue influence

Indicators (Data collection method*)

a. Mental health integrated into the District Health Plan (Case study: district profile);
% increase in financial resources allocated to mental health released on time and available to spend (Case study: district profile)
b. # stock outs in last 30 days for essential psychotropic medications outlined in the MHCP (Case study: facility profile)
c. Health information system contains key mental health indicators as outlined in the MHCP (Case study: district profile);
Mental health data reported in district quarterly and annual health sector performance reviews in relation to service plans and used for ongoing planning in district (case study: district profile)
f. Mental health programme co-ordinator in post prior to MHCP implementation (Case study: district profile)
g. # health care organisation staff are aware of mental illness, have reduced stigma and are willing to engage with programme (Case study: district profile)
h. All staff receive quality supervision on a regular basis as defined by the MHCP and guidelines (Case study: training and supervision evaluation; Case study: process evaluation)
g. Adequate numbers of human resources as per the MHCP are available at primary and community levels (Case study: facility profile)
h. Appropriate content of supervision ; Feedback from participants on quality of supervision (Case study: training and supervision evaluation)
i. Able to deliver good quality training (Case study: training and supervision evaluation)
j. Mental health professionals aware of new system, configuration / new roles, and willing to provide specialist care to complex cases (Case study: process evaluation)
k. Change in knowledge and attitudes pre-and post training (Case study: training and supervision evaluation)
l. Medications are available at all clinics 95% of time (disaggregated by clinic and type of medication) (Case study: facility profile); Staff trained in psychosocial interventions are available at the facility (Case study: facility profile)

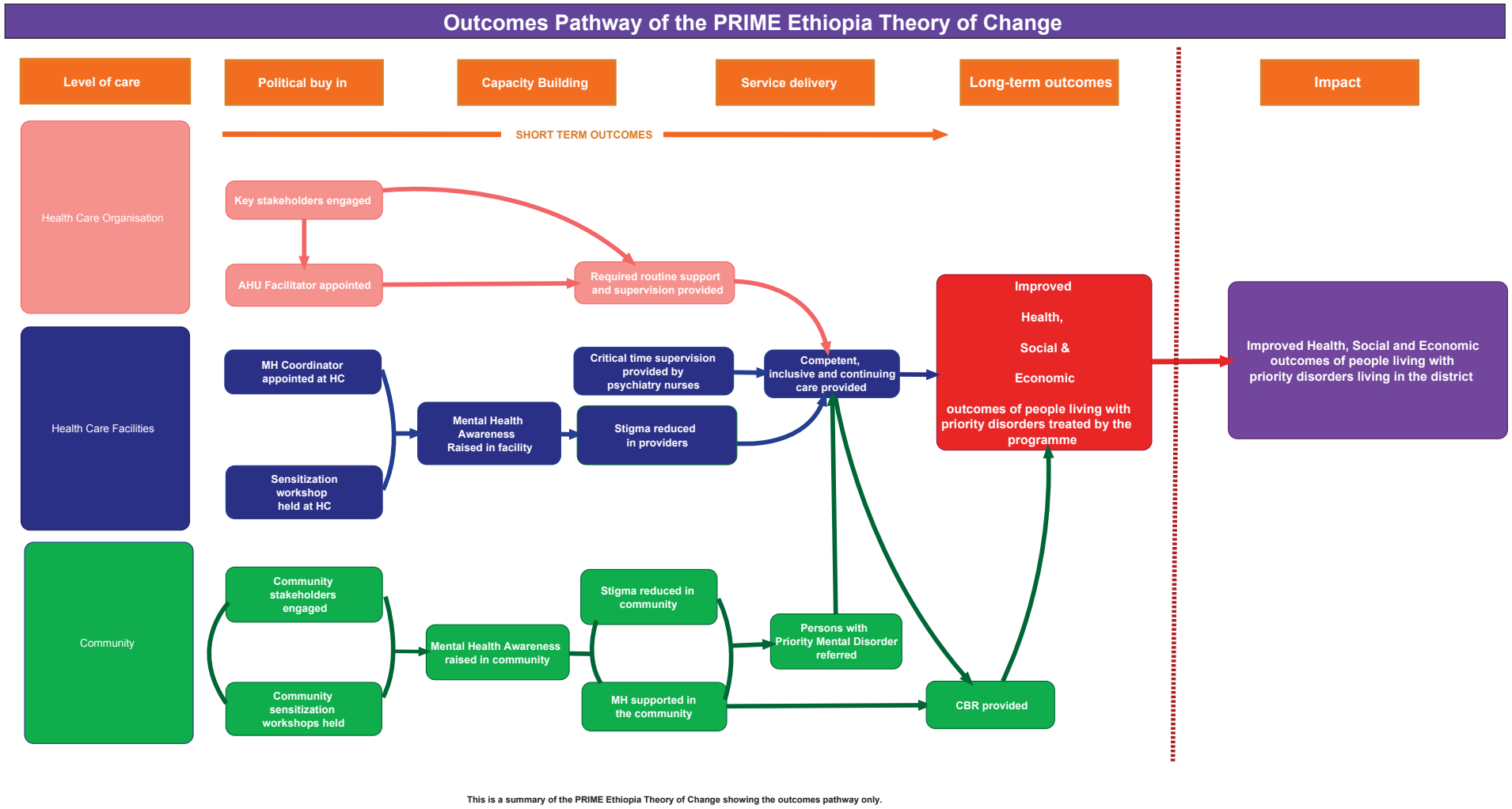
Indicators (Data collection method*) continued

m. Satisfaction with referral system from PHC service providers (Case study: process evaluation)
n. Service users' perception of accessibility and acceptability of services (Cohort: qualitative)
o. Increased no. of people correctly receiving evidence-based treatment (Facility Detection Survey); Referrals to specialists are made, % retained in care at 12 months or achieved remission by 12 months, Screening for side effects occurs (Cohort); Medication is changed in response to change in clinical status (Case study: training and supervision evaluation)
p. Increased no. and proportion of people correctly identified/diagnosed with depression and alcohol use (Facility Detection Survey); Increase in % mental health case load as a proportion of total PHC headcount (Case study: facility profile)
q. Change in knowledge and attitudes pre-and post training (Case study: training and supervision evaluation)
r. Components of CBR are being provided in the community as per the MHCP (Case study: community profile)
s. Service users' perception of accessibility and acceptability of services (Cohort: qualitative)
t. # of patients who received psychosocial interventions at community level % retained in care at 12 months or achieved remission by 12 months, CHW make referrals to PHC (Cohort)
u. Increased number of cases detected and managed by CHW (Case study: community profile)
v. Increase in help-seeking and earlier presentation at clinic (Facility detection survey)
w. Improved MH literacy and decrease in stigma, Community members are aware of local availability of treatment (Community survey), Decreased reported stigma by people with priority disorders (Cohort)
x. Improved health, social and economic outcomes of people living with priority mental disorders (Cohort)
y. Changes in environmental, policy, social and political contexts are monitored throughout implementation (Case study: district profile)
z. Increased coverage of evidence based mental health services (Community survey, Cohort)

*see De Silva et al 2014 for more details

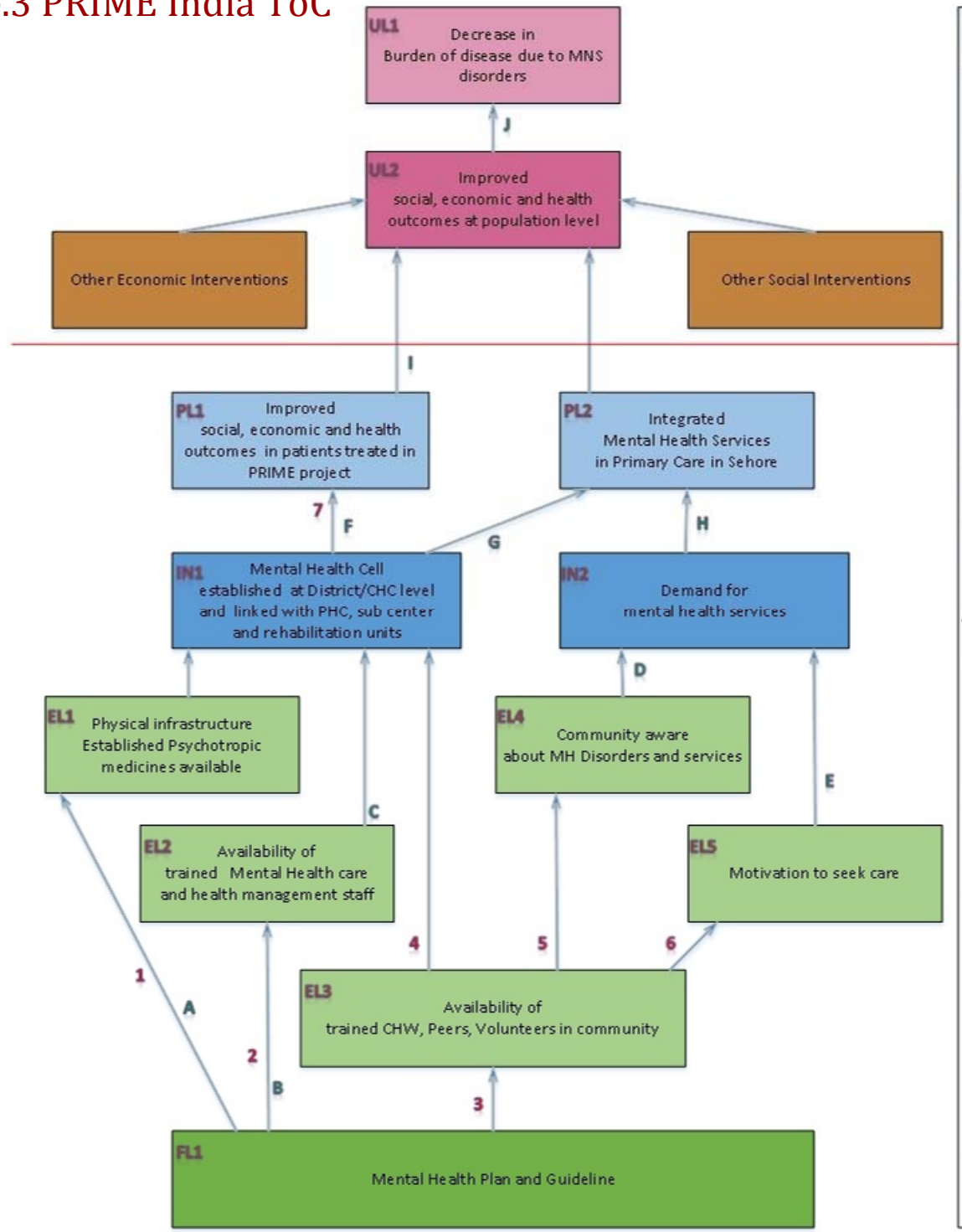
Last updated: 20th June 2014

Appendix 4.2 PRIME Ethiopia ToC



This is a summary of the PRIME Ethiopia Theory of Change showing the outcomes pathway only.

Appendix 4.3 PRIME India ToC



Legends

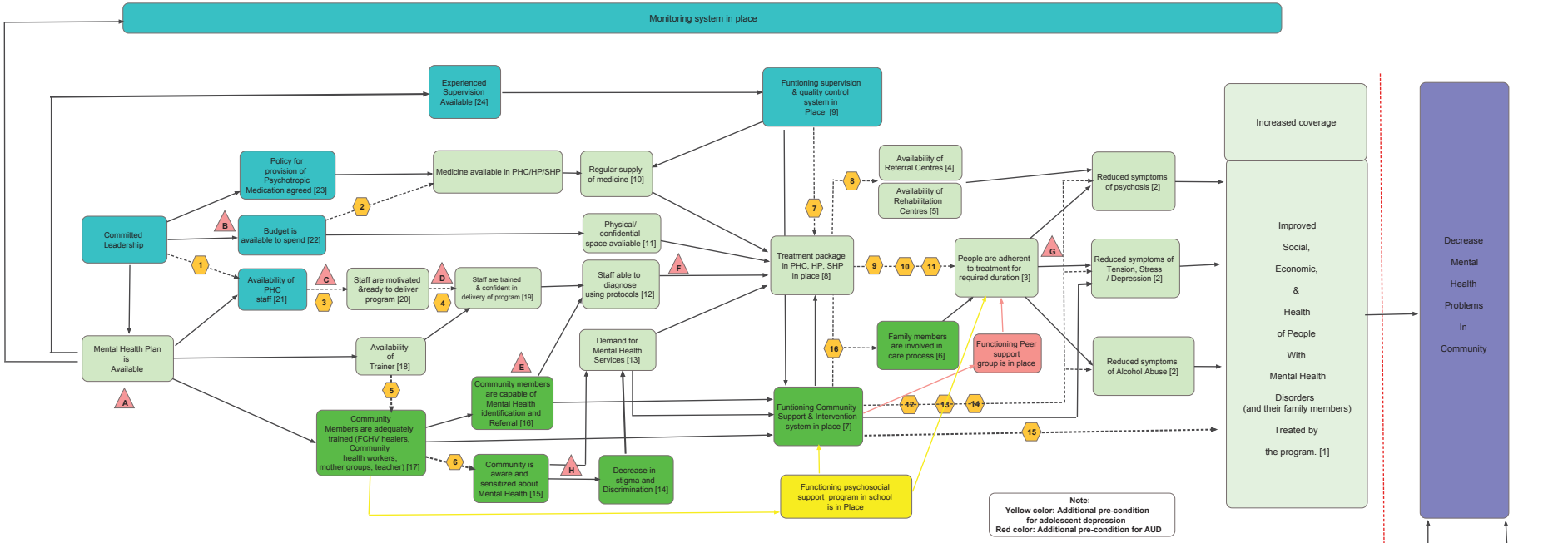
Interventions in TOC

1. Procurement of Psychotropic medications and setting up a space for mental health interventions in the facilities
2. Training of medical officers/mental health managers
3. Recruitment and training of Front-line workers
4. Identification of patients with priority mental disorders, provision of mental health first aid, follow-up of patients and provision of rehabilitation services
5. Community based interventions to improve mental health literacy
6. Community based interventions to reduce stigma and improve help-seeking behavior
7. Pharmacological management of priority mental disorders and provision of psycho-social interventions

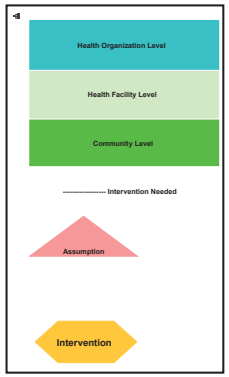
Assumptions in TOC

- **A** Budget provisions made and money is made available for setting up space and procurement of psychotropic medications
- **B** Political buy-in and support to endorse mental health guidelines and support its implementation
- **C** General health staff (MOs and FLWs) willing to provide mental health services at community and facility level
- **D** Improvement in mental health literacy would improve help-seeking behavior resulting in demand for services
- **E** Stigma reduction interventions would improve help-seeking behavior resulting in demand for service
- **F** Patients receive regular follow-up and are adherent to treatment and in these patients interventions lead to reduction in disease severity and disability severity
- **G** Mental Health Cell is accessible
- **H** Services offered in Mental Health Cell are acceptable and affordable

Appendix 4.4 PRIME Nepal ToC



LEGENDS



INDICATORS

[1] Pre-post survey, Employment rate
[2] Number of symptoms reduced, number of suicide attempts
Police case and road accident (only for AUD)
[3] Defaulter rate, Relapse rate; Medicine record and report, Family record about medicine consumption
[4] Referral Slip and Feedback
[5] Referral slips
[6] No of patients who come with family members to health facility, Improvement of patient, Field report
[7] No of trained community member and source of patient in health centre
[8] Number of trained staff available, drugs available, Protocol available
Recording and reporting tools, and Alternative trained manpower
[9] Supervision check list, Schedule, Report, Suggestion and feedback provided; Supervision record
[10] Stock register, ASL(authorized stock level), EOP(emergency order point)
[11] Availability of separate room for MH treatment
[12] Protocal in place, Register, Prescription slip O\C
[13] Client flow, Community participation on mental health training
meeting, seminar in the community
[14] Interview/Survey result, client flow
[15] Patient flow and Survey result
[16] Number of people referred to health facilities and Number of cases positively diagnosed in the PHC
[17] No of trained human resource and frequency of training
[18] No of trainer available
[19] Pre test and post test result, skills test, Exposure visit to hospital ,case study
[20] Performance appraisal by DPHO
[21] Fulfillment of sanctioned post, government commitment
[22] Budget allocation and timely release
[23] MOU with MOHP
[24] Appointment of supervisor, Report and checklist

ASSUMPTIONS

A - Mental health experts are involved in process

B - Ministry of Health and Population has money to spend

C - Motivation is possible without monetary incentives

D - Trained staff is not transferred or new staff is trained

E - Community participation for transportation of the patients

F - Trained staff able to distinguish real and fake drug users

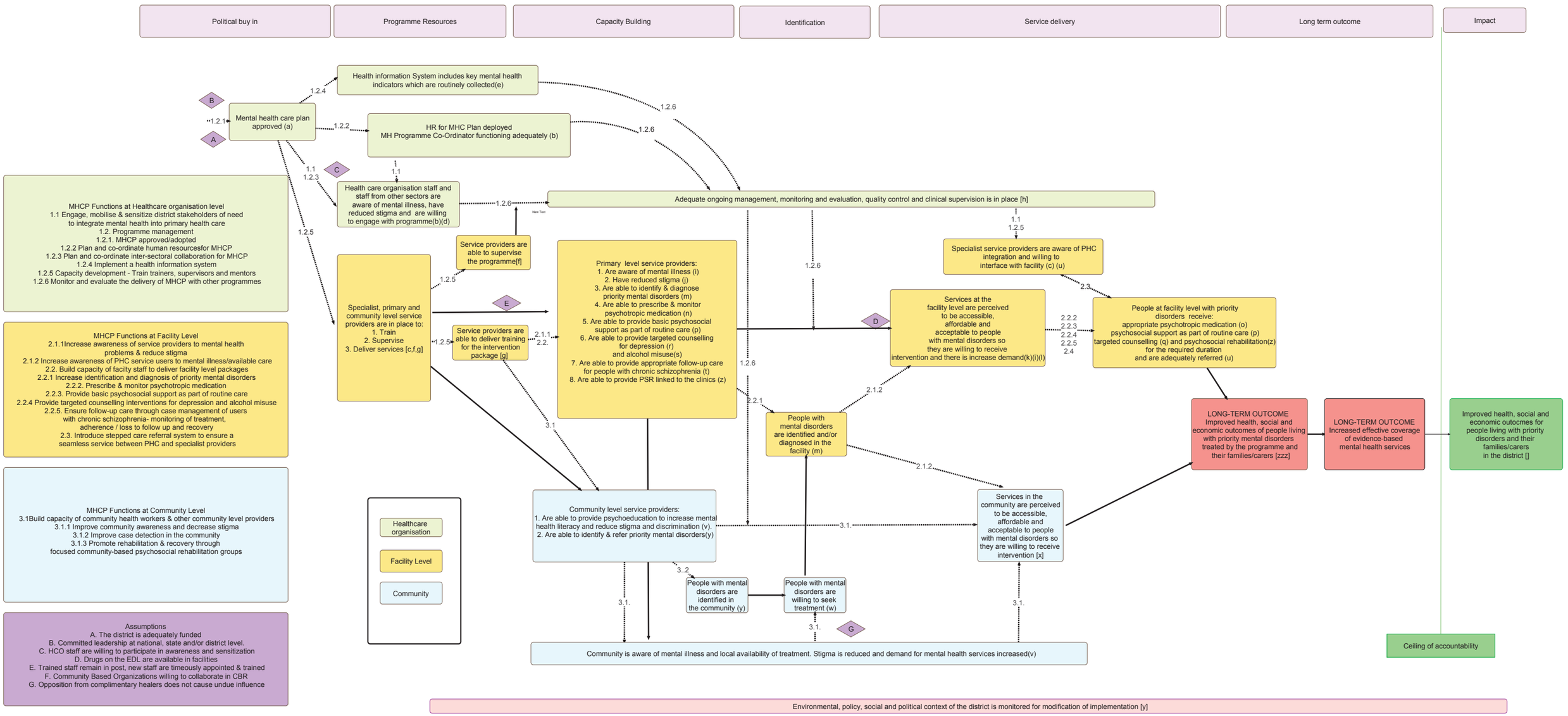
G - Treatment leads to reduced mental health problems

H - Involvement of user groups for awareness raising and destigammtization process

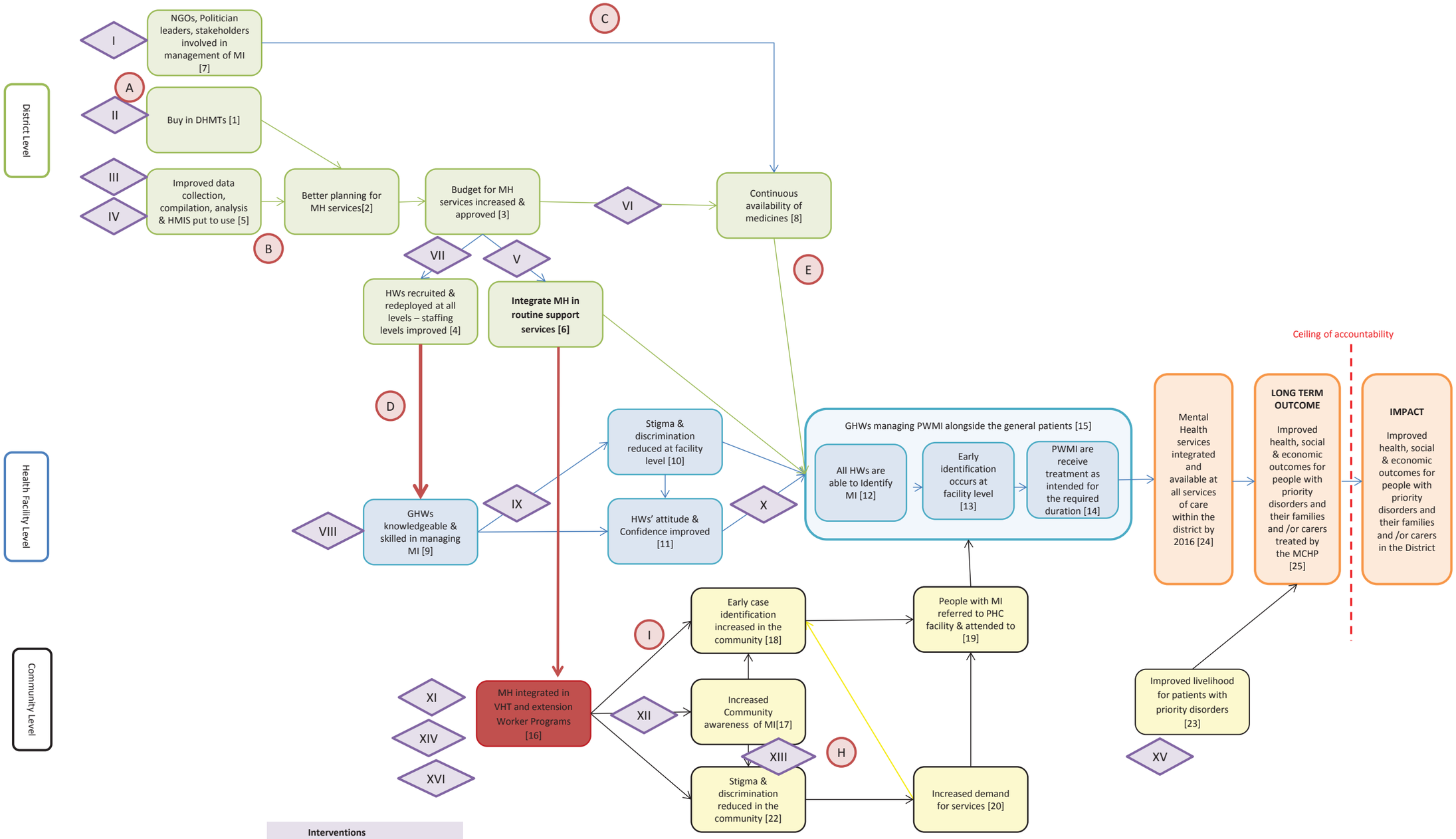
INTERVENTIONS

1 - Program orientation
2 - Procurement
3 - Orientation on mental health and (non- monetary) incentives
4 - Training course
5 - Training course
6 - Awareness and sensitization program
7 - Use of supervision checklist and guide
8 - Coordination and feedback
9 - Intervention provided
10- Rehabilitation
11 - Follow-up
12 - Community reintegration activities conducted
13 - Psychosocial interventions given
14 - Regular supervision
15 - Linkage to livelihood programs
16 - Psycho-education to family members

Appendix 4.5 PRIME SA ToC



Appendix 4.6 PRIME Uganda ToC



	Interventions
I	Sensitize partners including PNFPs
II	Sensitize district administrators
III	Training in HMIS
IV	Avail HMIS logistics
V	MH focal person joins the support supervision team
VI	Procure drugs
VII	Recruit and deploy staff
VIII	Standardized training for HWs

	Interventions
IX	Mentoring & support of the GHWs e.g. protection,& incentive
X	Avail guidelines at facility level screening for CMDs
XI	Media program
XII	Sensitize community
XIII	Community dialogue for mental health
XIV	Develop appropriate IEC materials
XV	Form & Facilitate formation of support groups
XVI	Sensitize & train VHT & extension workers to identify priority disorders

	Indicators
1	Participation of key stakeholder in meetings, reported buy in on interview
2	MH included in the approved work plans
3	Proportion of budget allocated to MH
4	Proportion of facilities with qualified HWs work plans
5	HIMS records and reports
6	Mental health in reports of DHMT, Representation of MH on DHMT , MH regularly on the agenda of DHMT
7	Level of participation &MH activities in their work plans work plans
8	Days of stock outs and medication on essential drug list
9	Appropriate diagnoses and treatment
10	Change in stigma and discrimination of HCW before/after training
11	Change in perceived confidence and attitude of HCW before/after training
12	Appropriate diagnosis & treatment

	Indicators
13	Appropriate diagnosis & treatment
14	higher attendance recorded in HIMS
15	Attendance records
16	Referrals from VHTs & reports
17	People aware about the causes & nature of MI
18	No. of patients referred to PHC facility
19	Increased no. of clients receiving MH care
20	No. of PWMI benefiting in existing district programs
21	Referrals from Extension workers
22	Increase in no. of people presenting for mental disorders in facilities.
23	Level of participation in the activities of support groups
24	Health Facility records & reports
25	General Socio-economic welfare of PWMI and their families

	Assumptions
A	The District is adequately funded
B	Increased utilization of data
C	Service standards available
D	HWs available on the market: MH is a priority
E	NMS has adequate stocks & delivers on time
F	Time & space available
G	Health care seeking behavior improve with increased awareness
H	Awareness improves attitude toward the mentally ill
I	Opposition from complimentary healers does not cause undue influence

Appendix 5.1 PRIME Nepal Calibrated Data

Facility Number	Quarter	Primary care service utilisation for mental illness	Medication supply	Supervision (facility)	Supervision (community)	Trained human resources (facility)	Trained human resources (community)	Facility psychosocial interventions	mhGAP	Referral to tertiary care	Community identification	Community awareness and stigma reduction
1	3	0.10	0.00	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
1	9	0.09	0.00	0.00	0.00	0.95	0	0.67	0.00	1.00	0.00	0.05
1	12	0.30	0.83	0.50	0.00	0.95	1	1.00	0.00	1.00	0.94	0.14
1	16	0.19	1.00	1.00	1.00	0.95	1	1.00	1.00	1.00	0.89	0.60
1	22	1.00	1.00	1.00	1.00	0.95	1	1.00	1.00	1.00	0.74	0.62
1	25	0.99	1.00	0.67	1.00	0.95	1	1.00	1.00	1.00	0.00	0.62
1	29	0.99	0.63	0.33	0.50	0.99	1	1.00	1.00	1.00	0.00	0.62
1	32	1.00	0.79	0.17	0.17	0.99	1	1.00	1.00	1.00	0.34	0.62
1	35	0.82	0.83	0.33	0.17	0.99	1	1.00	1.00	1.00	0.34	0.62
1	38	0.96	0.83	1.00	0.17	0.99	1	1.00	1.00	1.00	0.59	0.62
2	3	0.07	0.00	0.00	0.00	0.05	0	0.00	0.00	0.00	0.00	0.05
2	9	0.00	0.00	0.00	0.00	1.00	0	0.00	0.00	1.00	0.00	0.05
2	12	0.68	1.00	0.00	0.00	1.00	1	1.00	1.00	1.00	0.59	0.05
2	16	0.96	1.00	1.00	0.67	0.55	1	1.00	1.00	1.00	0.80	0.88
2	22	0.82	1.00	1.00	1.00	0.55	1	1.00	1.00	1.00	0.59	0.89
2	25	0.67	0.75	0.67	1.00	0.55	1	1.00	1.00	1.00	0.45	0.89
2	29	0.59	0.83	0.33	0.50	0.55	1	0.89	1.00	1.00	0.45	0.89
2	32	0.90	0.58	0.17	0.17	0.95	1	1.00	1.00	1.00	0.59	0.89
2	35	0.78	0.42	0.33	0.17	0.95	1	1.00	1.00	1.00	0.59	0.89
2	38	0.98	0.83	1.00	0.17	0.89	1	1.00	1.00	1.00	0.86	0.89
3	3	0.00	0.00	0.00	0.00	0.05	0	0.00	0.00	0.00	0.00	0.05
3	9	0.22	0.00	0.00	0.00	0.75	0	0.67	0.00	1.00	0.00	0.05
3	12	0.61	1.00	0.17	0.00	0.89	1	1.00	0.00	1.00	0.59	0.52
3	16	0.58	0.83	0.83	0.67	0.89	1	1.00	1.00	1.00	0.91	0.96
3	22	0.91	0.83	1.00	1.00	0.95	1	1.00	1.00	1.00	0.34	0.99
3	25	0.28	0.83	0.67	1.00	0.95	1	1.00	1.00	1.00	0.00	0.99
3	29	0.91	0.75	0.33	0.50	0.98	1	1.00	1.00	1.00	0.00	0.99
3	32	0.98	0.83	0.17	0.17	0.95	1	1.00	1.00	1.00	0.34	0.99
3	35	0.90	0.83	0.33	0.17	0.95	1	1.00	1.00	1.00	0.34	0.99
3	38	0.94	0.83	1.00	0.17	0.89	1	1.00	1.00	1.00	0.59	0.99
4	3	0.00	0.83	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
4	9	0.00	0.00	0.00	0.00	0.95	0	1.00	1.00	1.00	0.00	0.05
4	12	0.17	0.83	0.17	0.00	0.89	1	1.00	0.00	1.00	0.86	0.05
4	16	0.90	0.83	0.83	1.00	0.98	1	1.00	1.00	1.00	0.99	0.57
4	22	0.28	0.83	1.00	1.00	0.98	1	1.00	0.75	1.00	0.59	0.83
4	25	0.73	0.83	0.67	1.00	0.98	1	1.00	1.00	1.00	0.00	0.83
4	29	0.89	0.83	0.33	0.50	0.98	1	1.00	1.00	1.00	0.59	0.88
4	32	0.82	0.67	0.17	0.17	0.95	1	1.00	1.00	1.00	0.74	0.88
4	35	0.47	0.63	0.33	0.17	0.89	1	1.00	1.00	1.00	0.74	0.88
4	38	0.81	0.83	1.00	0.17	0.89	1	1.00	1.00	1.00	0.80	0.88

5	3	0.75	0.00	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
5	9	0.09	0.00	0.00	0.00	0.25	0	1.00	0.00	1.00	0.00	0.05
5	12	0.69	0.83	0.17	0.00	0.25	1	0.67	0.00	1.00	0.86	0.05
5	16	1.00	0.83	0.83	1.00	0.25	1	1.00	1.00	1.00	0.74	0.05
5	22	1.00	0.79	1.00	1.00	0.55	1	1.00	1.00	1.00	0.74	0.85
5	25	0.94	0.83	0.67	1.00	0.75	1	1.00	1.00	1.00	0.45	0.85
5	29	0.45	0.54	0.33	0.50	0.89	1	1.00	1.00	1.00	0.45	0.96
5	32	0.71	0.67	0.17	0.17	0.98	1	1.00	1.00	1.00	0.00	0.96
5	35	0.96	0.71	0.33	0.17	0.98	1	1.00	1.00	1.00	0.00	0.96
5	38	0.94	0.83	1.00	0.17	0.98	1	1.00	1.00	1.00	0.00	0.96
6	3	0.00	0.00	0.00	0.00	0.05	0	0.00	0.00	0.00	0.00	0.05
6	9	0.00	0.00	0.00	0.00	0.38	0	1.00	0.00	1.00	0.00	0.05
6	12	0.47	0.67	0.17	0.00	0.55	1	0.67	0.00	1.00	0.59	0.05
6	16	0.89	1.00	0.83	0.83	0.55	1	1.00	1.00	1.00	0.59	0.05
6	22	0.87	0.83	1.00	1.00	0.55	1	1.00	1.00	1.00	0.34	0.60
6	25	0.99	0.83	0.67	1.00	0.38	1	1.00	1.00	1.00	0.00	0.60
6	29	0.99	0.71	0.33	0.50	0.75	1	1.00	1.00	1.00	0.34	0.73
6	32	0.98	0.83	0.17	0.17	0.95	1	1.00	1.00	1.00	0.34	0.73
6	35	0.87	0.83	0.33	0.17	0.75	1	1.00	1.00	1.00	0.34	0.73
6	38	0.93	0.83	1.00	0.17	0.89	1	1.00	1.00	1.00	0.00	0.73
7	3	0.08	0.00	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
7	9	0.00	0.00	0.00	0.00	0.89	0	1.00	0.00	1.00	0.00	0.05
7	12	0.34	0.67	0.17	0.00	0.98	1	1.00	0.00	1.00	0.89	0.05
7	16	1.00	1.00	0.83	0.67	0.75	1	1.00	1.00	1.00	1.00	0.87
7	22	0.87	1.00	1.00	1.00	0.95	1	1.00	1.00	1.00	0.69	0.92
7	25	0.61	0.83	0.67	1.00	0.75	1	0.67	1.00	1.00	0.00	0.96
7	29	0.78	0.67	0.33	0.50	0.75	1	1.00	1.00	1.00	0.00	0.96
7	32	0.94	0.83	0.17	0.17	1.00	1	1.00	1.00	1.00	0.00	0.96
7	35	0.83	0.83	0.33	0.17	0.99	1	1.00	1.00	1.00	0.00	0.96
7	38	0.69	0.83	1.00	0.17	0.98	1	1.00	1.00	1.00	0.00	0.96
8	3	0.12	0.00	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
8	9	0.08	0.00	0.00	0.00	1.00	0	0.67	0.00	1.00	0.00	0.05
8	12	0.24	0.83	0.17	0.00	1.00	1	1.00	0.00	1.00	0.00	0.05
8	16	0.17	1.00	0.83	0.67	0.72	1	1.00	1.00	1.00	0.96	0.65
8	22	0.24	1.00	1.00	1.00	0.99	1	1.00	1.00	1.00	0.45	0.67
8	25	0.10	0.83	0.67	1.00	0.69	1	1.00	1.00	1.00	0.45	0.67
8	29	0.07	0.75	0.33	0.50	1.00	1	1.00	1.00	1.00	0.00	0.67
8	32	0.36	0.83	0.17	0.17	1.00	1	0.67	1.00	1.00	0.34	0.67
8	35	0.35	0.75	0.33	0.17	0.96	1	1.00	1.00	1.00	0.34	0.67
8	38	0.44	0.83	1.00	0.17	0.99	1	1.00	1.00	1.00	0.59	0.67
9	3	0.00	0.00	0.00	0.00	0.05	0	0.00	0.00	0.00	0.00	0.05
9	9	0.07	0.00	0.00	0.00	0.38	0	1.00	0.00	1.00	0.00	0.05
9	12	0.23	0.83	0.17	0.00	0.38	1	1.00	0.00	1.00	0.00	0.05
9	16	0.99	0.83	0.83	1.00	0.38	1	1.00	1.00	1.00	0.00	0.29
9	22	1.00	1.00	1.00	1.00	0.75	1	1.00	1.00	1.00	0.59	0.57
9	25	1.00	0.83	0.67	1.00	0.38	1	1.00	1.00	1.00	0.59	0.57
9	29	1.00	0.50	0.33	0.50	0.75	1	1.00	1.00	1.00	0.59	0.57
9	32	1.00	0.54	0.17	0.17	0.95	1	1.00	1.00	1.00	0.00	0.57
9	35	0.99	0.67	0.33	0.17	0.99	1	1.00	1.00	1.00	0.00	0.57
9	38	1.00	0.83	1.00	0.17	0.89	1	0.89	1.00	1.00	0.00	0.57

10	3	0.00	0.00	0.00	0.00	0.05	0	0.00	0.00	1.00	0.00	0.05
10	9	0.00	0.00	0.00	0.00	0.89	0	0.33	0.00	1.00	0.00	0.05
10	12	0.32	0.83	0.50	0.00	0.89	1	0.33	1.00	1.00	0.80	0.05
10	16	0.70	1.00	0.33	1.00	0.89	1	0.78	1.00	1.00	0.83	0.14
10	22	0.82	0.96	0.50	1.00	0.89	1	0.67	1.00	1.00	0.74	0.85
10	25	0.86	1.00	0.67	1.00	0.89	1	0.67	1.00	1.00	0.59	0.85
10	29	1.00	0.67	0.33	0.50	0.75	1	0.50	1.00	1.00	0.80	0.85
10	32	1.00	0.67	0.17	0.17	0.98	1	1.00	1.00	1.00	0.94	0.85
10	35	0.95	0.75	0.33	0.17	0.89	1	1.00	1.00	1.00	0.94	0.85
10	38	0.96	0.83	1.00	0.17	0.75	1	1.00	1.00	1.00	0.97	0.85